Exhibit B

Form of Development Agreement

EXECUTION VERSION

DEVELOPMENT AGREEMENT

by and between

GREENFIELD BIOVENTURES L.P.

and

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DEVELOPMENT AGREEMENT

This **DEVELOPMENT AGREEMENT** (this "**Agreement**") is entered into as of February 11, 2020 by and between **GREENFIELD BIOVENTURES L.P.**, a Delaware limited partnership having an address at One Stamford Forum, Stamford, Connecticut 06901 ("**Greenfield**"), and [redacted], a Delaware corporation, having an address at [redacted] ("**Technology Partner**"). Greenfield and Technology Partner are sometimes referred to individually as a "**Party**" and collectively as the "**Parties**".

RECITALS

WHEREAS, Greenfield has rights to the Licensed Compound (as defined below) and desires to develop a pharmaceutical product that is a formulation of the Licensed Compound administered via an auto injector as a drug/device combination product.

WHEREAS, Technology Partner has rights to the Auto Injector (as defined below) and has resources and expertise in the development of drug/device combination products.

WHEREAS, (a) Greenfield desires to license to Technology Partner, and Technology Partner desires to license from Greenfield, the Greenfield Technology (as defined below), and (b) Technology Partner desires to license to Greenfield, and Greenfield desires to license from Technology Partner, the Technology Partner Technology (as defined below), for the consideration and on the terms set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

"**Accepted New Drug Application**" means a New Drug Application in respect of a Product in the U.S. that has been accepted for filing by the FDA for review.

"**Acquiror**" has the meaning set forth in Section 13.5.

"**Advisory Committee Meeting**" means an FDA public advisory committee meeting to discuss New Drug Applications and application supplements to such New Drug Applications.

"**Affiliate**" means, with respect to either Party, any person, firm, trust, corporation, partnership or other entity or combination thereof that directly or indirectly controls, is controlled by or is under common control with such Party; for purposes of this definition, the term "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") meaning direct or indirect ownership of fifty percent (50%) or more, including ownership by one or more trusts with substantially the same beneficial interests, of the voting and equity rights of such person, firm, trust, corporation, partnership or other entity or combination thereof, or the power to direct the management of such person, firm, trust, corporation, partnership or other entity or combination thereof. For purposes of this Agreement, "**Affiliate**" in the case of Greenfield,

specifically includes Parent, but excludes The Purdue Frederick Company, Inc., a New York corporation d/b/a The Purdue Frederick Company.

"**Alternative Technology Partner Subcontractor**" has the meaning set forth in Section 4.3.

"**Apparent Defects**" has the meaning set forth in Section 6.3.

"**Approval Order**" means an order of the Bankruptcy Court, in form and substance reasonably acceptable to the Parties, approving Greenfield's and Parent's entry into this Agreement.

"**Auto Injector**" means Technology Partner's proprietary auto injector, having the specifications set forth on Schedule 2.

"**Bankruptcy Code**" means title 11 of the United States Code, 11 U.S.C. §§ 101-1532, as amended from time to time, as applicable to the Chapter 11 Cases.

"**Bankruptcy Court**" means the United States Bankruptcy Court for the Southern District of New York or such other court as shall have jurisdiction over the Chapter 11 Cases.

"**Bankruptcy Rules**" means the Federal Rules of Bankruptcy Procedure, as applicable to the Chapter 11 Cases, promulgated under section 2075 of the Judicial Code and the general, local, and chambers rules of the Bankruptcy Court, each as amended from time to time.

"**Breaching Party**" has the meaning set forth in Section 11.6.

"**Business Day**" means any day other than a day on which the commercial banks in New York City are authorized or required to be closed.

"**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term commences on the Effective Date and ends on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term commences on January 1 of the year in which the Term ends and ends on the last day of the Term.

"**Change of Control**" means, with respect to either Party, (a) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (b) a merger (including a reverse triangular merger), consolidation, share exchange or other similar transaction involving such Party and any Third Party which results in the holders of the outstanding voting securities of such Party, or any Affiliate that controls such Party directly or indirectly, immediately before such merger, consolidation, share exchange or other similar transaction ceasing to hold more than fifty percent (50%) of the combined voting power of the surviving, purchasing or continuing entity immediately after such merger, consolidation, share exchange or other similar transaction, or (c) the acquisition by a person or entity, or group of persons or entities acting in concert, of more than fifty percent (50%) of the outstanding voting equity securities of such Party; in all cases of clauses (a)–(c), where such transaction is entered into with any person or group of persons other than the other Party or its Affiliates

"**Chapter 11 Cases**" means the bankruptcy cases filed on September 15, 2019 by Parent and certain of its affiliates (including Greenfield) under chapter 11 of the United States Code in the Bankruptcy Court and jointly administered under Case. Nos. 19-23649 (RDD) or any other proceedings superseding or related to the foregoing.

"**Claims**" has the meaning set forth in Section 9.1.

"**Clinical Studies**" means any research or clinical study using human subjects designed to evaluate biomedical or health-related outcomes, including a Phase 1 Study, a Phase 2 Study, a Phase 3 Study, a Phase 4 Study or variations of such studies (e.g., Phase 2/3). "**Clinical Studies**" excludes human factor research studies.

"**CMC Information**" means information related to the chemistry, manufacturing and controls of a product, as specified by the FDA and other applicable Regulatory Authorities, including under 21 C.F.R. § 312.23(a)(7).

"**Commercially Reasonable Efforts**" means, with respect to a Party's obligations under this Agreement, the carrying out of such obligations with a level of efforts and resources consistent with the commercially reasonable practices of a similarly sized company with a similarly-sized infrastructure to support and carry out operations in the pharmaceutical or biotechnology or medical device industry (as applicable) for the development or commercialization of a similarly situated product as Product at a similar stage of development or commercialization, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labeling, present and future market potential, competitive market conditions, the profitability of Product in light of pricing and reimbursement issues, including rebates under risk sharing schemes, and all other relevant factors.

"**Competitive Product**" means any pharmaceutical product, other than Product, that [redacted].

"**Confidential Information**" of a Party means any and all Information that is disclosed by or on behalf of such Party or its Affiliates to the other Party or its Affiliates under this Agreement, whether in oral, written, graphic, or electronic form, and any and all Information generated by such other Party or its Affiliates to the extent based on such disclosed Information.

"**Confidentiality Agreement**" means that certain letter agreement, dated January 23, 2018, between Parent and Technology Partner.

"**Contributing Party**" means, with respect to a Product and a Third Party Patent Claim, the Party contributing the applicable subject matter alleged to be infringing the Patent of such Third Party Patent Claim. For the avoidance of doubt, (a) Greenfield shall be the Contributing Party if such subject matter alleged to be infringing the Patent of such Third Party Patent Claim is the Licensed Compound, Pre-Filled Syringe or a pharmaceutical product that combines the Licensed Compound or Pre-Filled Syringe with an auto-injector device (including the Product but excluding the case where such infringement solely pertains to the Auto Injector), and (b) Technology Partner shall be the Contributing Party if such subject matter alleged to be infringing the Patent of such Third Party Patent Claim is the Auto Injector, or a pharmaceutical product that

combines the Auto Injector with a pharmaceutical compound (but excluding the Licensed Compound, or Pre-Filled Syringe).

"**Control**" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns or (b) has a license (other than a license granted to such Party under this Agreement), right or covenant to such material, Information, or intellectual property right, and in each case, has the ability to grant to the other Party access, a license or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

"**Default Notice**" has the meaning set forth in Section 11.6.

"**Defective**" means, with respect to Product for use in connection with Clinical Studies, that such Product does not, at the time that Greenfield receives the shipment of such Product, meet the quality requirements set out in the Product Specifications and/or Quality Agreement, and "**Defect**" shall be construed accordingly.

"**Develop**" or "**Development**" means, with respect to a Product, all activities related to research, preclinical and other non-Clinical Studies, test method development and stability testing, toxicology, formulation, manufacture process development, Clinical Studies, including manufacturing in support thereof (but excluding any commercial manufacturing), statistical analysis and report writing, the preparation and submission of New Drug Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval for such Product. When used as a verb, "**Develop**" means to engage in Development.

"**Development Committee**" has the meaning set forth in Section 3.2(a).

"**Development Fees**" has the meaning set forth in Section 4.4(a).

"**Development Plan**" has the meaning set forth in Section 4.2(a).

"**Development Report(s)**" has the meaning set forth in Section 4.6.

"**DHF**" means a compilation of records as described in 21 C.F.R. § 820.3(e). A DHF describes the design history of a finished medical device to satisfy the design control requirements of 21 C.F.R. § 820.30.

"**Dispute**" has the meaning in Section 12.1.

"**Distribution**", with a correlative meaning for "**Distribute**" and "**Distributing**", means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the commercialization and pre-launch, launch, promotion, detailing, marketing, pricing, reimbursement, sale, donation and distribution of Product, including strategic marketing, sales force detailing, advertising, and market and Product support, and all customer support, Product distribution, invoicing and sales activities; *provided, however*, "**Distribution**" excludes any activities relating to the manufacture of Product.

"**Dollars**" or "**$**" means U.S. dollars.

"**DMF**" means a drug master file as described in 21 C.F.R. § 314.420. A DMF is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

"**Effective Date**" has the meaning set forth in Section 11.1.

"**FD&C Act**" means the U.S. Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

"**FDA**" means the U.S. Food and Drug Administration or any successor entity.

"**Field**" means the prevention and/or reversal of the effects of opioid overdose.

"**File**," "**Filed**," or "**Filing**" means file, filed, or filing in the Chapter 11 Cases with the Bankruptcy Court.

"**GCP**" means the then-current good clinical practice standards and procedures promulgated or endorsed by the FDA as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," including related regulatory requirements imposed by the FDA and comparable regulatory standards, practices and procedures promulgated by other Regulatory Authorities having jurisdiction in the Territory, as such standards, practices and procedures may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"**GLP**" means the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C. F. R. Part 58, and comparable regulatory standards promulgated by other Regulatory Authorities having jurisdiction in the Territory, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"**GMP**" means the then-current standards relating to current good manufacturing practice for drugs, including fine chemicals, active ingredients, intermediates, bulk products or finished pharmaceutical products as set forth in (a) 21 U.S.C. § 351(a)(2)(B), in FDA regulations at 21 C.F.R. Parts 210 and 211, and comparable regulatory standards promulgated by other Regulatory Authorities having jurisdiction in the Territory or (b) the ICH Guidelines relating to the manufacture of active ingredients and finished pharmaceuticals, as such standards may be updated from time to time, including applicable quality guidelines promulgated under the ICH.

"**Governmental Authority**" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

"**Greenfield**" has the meaning set forth in the preamble.

"**Greenfield Indemnitees**" has the meaning set forth in Section 9.2.

"**Greenfield Inventions**" has the meaning set forth in Section 7.1(a).

"**Greenfield Know-How**" means all Information Controlled by Parent or Greenfield or any of its Subsidiaries during the Term that is not generally known and that is necessary or reasonably useful for the Development of a Product, but excluding any information to the extent covered or claimed by published Greenfield Patents.

"**Greenfield Patents**" means any Patent that (a) claims, generically or specifically, the Licensed Compound, Pre-Filled Syringe or any Product, or the manufacture or use in the Field of the Licensed Compound, Pre-Filled Syringe or any Product, and (b) that (i) is Controlled by Parent or Greenfield or any of its Subsidiaries as of the Effective Date, which such Patents are set forth in Schedule 3 hereto, (ii) is Controlled by Parent or Greenfield or any of its Subsidiaries during the Term and claims priority to a Patent Controlled by Parent or Greenfield or any of its Subsidiaries as of the Effective Date, or (iii) is Controlled by Parent or Greenfield or any of its Subsidiaries during the Term; [redacted]

"**Greenfield Technology**" means (a) the Greenfield Patents and (b) the Greenfield Know-How.

"**ICH**" means the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"**IND**" means an application filed with a Regulatory Authority for authorization to commence Clinical Studies, including (a) an Investigational New Drug Application required under § 505(j) of the FD&C Act and defined in 21 C.F.R. § 312.3 or any successor application or procedure filed with the FDA, (b) any equivalent of an Investigational New Drug Application in other countries or regulatory jurisdictions in the Territory, and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

"**Indemnified Party**" has the meaning set forth in Section 9.3.

"**Indemnifying Party**" has the meaning set forth in Section 9.3.

"**Information**" means any data, results, technology, business or financial information or information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, Clinical Study data and data resulting from

non-Clinical Studies), CMC Information, Regulatory Materials, stability data and other study data and procedures.

"**JRA Provision**" has the meaning set forth in Section 8.4(d).

"**Knowledge**" means, with respect to a Party, (a) the actual knowledge of the executive officers of such Party, or (b) the knowledge that any of such individuals reasonably should have gained through operating in the ordinary course of business with a level of efforts and resources consistent with the business practices of a similarly sized company with a similarly sized infrastructure to support and carry out its operations.

"**Laws**" means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

"**Licensed Compound**" means nalmefene or any salt (including specifically, nalmefene hydrochloride), pro-drug, metabolite, solvate, hydrate, polymorph or co-crystal thereof, or any improvement made by the Parties to nalmefene or any salt (including specifically, nalmefene hydrochloride), pro-drug, metabolite, solvate, hydrate, polymorph or co-crystal thereof, including any new dosage strengths or formulations (including those designed to enhance absorption).

"**MAF"** means a master file as described in 21 C.F.R. § 814.3(d). An MAF is a submission to the Center for Devices and Radiological Health that may be used as a reference source related to trade secret, confidential information, or other information or data associated with a medical device, device component, ingredient, subassembly, accessory, or facility or a manufacturing process, methodology, or procedure.

"**Negotiation Period**" has the meaning set forth in Section 2.6(a).

"**New Drug Application**" means an application submitted to the FDA under § 505(b) of the FD&C Act, 21 U.S.C. § 355(b), and defined in 21 C.F.R. §§ 314.3 and 314.50, including supplements to a New Drug Application.

"**Non-Breaching Party**" has the meaning set forth in Section 11.6.

"**Non-Governmental Authority**" means any public body or non-Governmental Authority with the authority to control, approve, recommend or otherwise determine pricing and reimbursement of pharmaceutical products, including those with authority to enter into risk sharing schemes or to impose retroactive price reductions, discounts, or rebates.

"**Outstanding Fees**" has the meaning set forth in Section 11.9.

"**Party**" or "**Parties**" has the meaning set forth in the preamble.

"**Parent**" means Purdue Pharma L.P.

"**Patents**" means (a) pending patent applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations,

additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; (c) any other patent application claiming priority to any of the foregoing anywhere in the world; and (d) extension, renewal or restoration of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof.

"**PDF**" means Adobe™ Portable Document Format sent by electronic mail.

"**Pharmacovigilance Agreement**" has the meaning set forth in Section 4.10.

"**Phase 1 Study**" means a human clinical trial with the endpoint of determining initial tolerance, safety or pharmacokinetic information in single dose, single ascending dose, multiple dose or multiple ascending dose regimens, as described in 21 C. F. R. § 312.21(a) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"**Phase 2 Study**" means a human clinical trial, the principal purpose of which is a preliminary determination of safety and efficacy in the target patient population over a range of doses and dose regimens, as described in 21 C. F. R. § 312.21(b) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"**Phase 3 Study**" means a human clinical trial for an indication on a sufficient number of subjects that is designed to establish that such compound or product is safe and efficacious for its intended use, and to determine warnings, precautions and adverse reactions that are associated with the compound or product in the dosage range to be prescribed, and to support regulatory approval of such compound or product for such indication or label expansion of such compound or product, as described in 21 C.F.R. § 312.21(c) (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"**Phase 4 Study**" means a human clinical trial as described in 21 C.F.R. § 312.85 (or its successor regulation) or the equivalent thereof in any jurisdiction outside the U.S.

"**Pre-Filled Syringe**" means Licensed Compound, filled and finished in pre-filled syringe bodies incorporating a needle and protective cap.

"**Product**" means any pharmaceutical product (including all presentations, dosages and formulations) for use in the Field derived from Development of a Pre-Filled Syringe incorporated into the Auto Injector as a drug/device combination product.

"**Product Specifications**" has the meaning set forth in Section 6.2.

"**Program**" means the program for Development of Product in accordance with the Development Plan and this Agreement.

"**Project Leader**" has the meaning set forth in Section 3.1(a).

"**Protective Order**" means the protective order entered by the Bankruptcy Court in the Chapter 11 Cases.

"**Publication**" has the meaning set forth in Section 10.3.

"**Quality Agreement**" has the meaning set forth in Section 6.7.

"**Regulatory Approval**" means, with respect to a Product in a country in the Territory, any and all approvals (including New Drug Applications), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially Distribute, sell or market such Product in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto) and (c) labeling approval.

"**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority or Non-Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

"**Regulatory Materials**" means applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority to Develop, manufacture, market, sell or otherwise Distribute Product in the Territory.

"**ROFN Notice**" has the meaning set forth in Section 2.6(a).

"**Step-in Notice**" means a written notice by Technology Partner of its election to exercise a step-in right as provided in Section 11.11.

"**Sublicensee**" means any entity to which a sublicense is validly granted pursuant to Section 2.1(b) or Section 2.2(b).

"**Subsidiary**" means, with respect to either Party, any person, firm, trust, corporation, partnership or other entity or combination thereof that is, directly or indirectly, controlled by (a) Technology Partner, with respect to Technology Partner, or (b) Greenfield or Parent, with respect to Greenfield; for purposes of this definition, the term "controlled by" means direct or indirect ownership of fifty percent (50%) or more of the voting and equity rights of such person, firm, trust, corporation, partnership or other entity or combination thereof, or the power to direct the management of such person, firm, trust, corporation, partnership or other entity or combination thereof.

"**Target Date**" means [redacted], which date may be updated from time-to-time by the Development Committee pursuant to Section 3.2(a)(iii).

"**Technology Partner**" has the meaning set forth in the preamble.

"**Technology Partner Indemnitees**" has the meaning set forth in Section 9.1.

"**Technology Partner Inventions**" has the meaning set forth in Section 7.1(b).

"**Technology Partner Know-How**" means all Information Controlled by Technology Partner or any of its Affiliates during the Term that is not generally known and that is necessary

or reasonably useful for the Development of a Product, but excluding any information to the extent covered or claimed by published Technology Partner Patents.

"**Technology Partner Patents**" means any Patent that (a) claims, generically or specifically, the Auto Injector or any Product, or the manufacture or use in the Field of the Auto Injector or any Product and is (b) (i) Controlled by Technology Partner or its Affiliates as of the Effective Date, which Patents are set forth in Schedule 1 hereto, (ii) Controlled by Technology Partner or its Affiliates during the Term and claims priority to a Patent Controlled by Technology Partner or its Affiliates as of the Effective Date, or (iii) Controlled by Technology Partner or its Affiliates during the Term; [redacted] Technology Partner Patents specifically exclude any Patents licensed to Technology Partner pursuant to Section 2.1, including the Greenfield Patents.

"**Technology Partner Subcontractors**" has the meaning set forth in Section 4.3.

"**Technology Partner Technology**" means (a) the Technology Partner Patents and (b) the Technology Partner Know-How.

"**Term**" has the meaning set forth in Section 11.2.

"**Territory**" means the U.S.

"**Territory Infringement**" has the meaning set forth in Section 7.5(a)

"**Third Party**" means any entity other than the Parties or an Affiliate of either of them.

"**Third Party Patent Claim**" has the meaning set forth in Section 7.6.

"**U.S.**" means the United States of America, including all possessions and territories thereof.

ARTICLE 2
LICENSES

2.1 Licenses to Technology Partner.

(a) **License Grant to Technology Partner.** Subject to the terms and conditions of this Agreement, Greenfield hereby grants to Technology Partner an exclusive (subject to Section 2.3), fully paid, royalty-free license, with the right to grant sublicenses solely as permitted under Section 2.1(b), under the Greenfield Technology, solely (i) to Develop, register, use, research, reproduce, modify, and make derivatives of Products for use in the Field and in and for the Territory in accordance with and to carry out activities under this Agreement and the Development Plan, and (ii) to manufacture, have manufactured, make and have made Products for use by, and

sale to, Greenfield, in the Field and in and for the Territory, including in connection with Clinical Studies.

(b) **Sublicense Rights.** Technology Partner may grant sublicenses of the licenses granted in Section 2.1(a) only to (i) its Affiliates, *provided* that any such sublicense automatically terminates if such person, corporation, partnership or entity ceases to be an Affiliate of Technology Partner, and (ii) subject to Section 4.3, Third Parties with the prior written consent of Greenfield, such consent not to be unreasonably withheld. Any and all sublicenses with a Sublicensee shall be subject to the following requirements (x) Technology Partner shall be responsible for each of its Sublicensees' compliance with the terms hereof and shall remain responsible for all of its obligations hereunder and (y) each sublicense agreement with a Sublicensee granted after the Effective Date shall (1) be in writing, and (2) be subject to and materially consistent with the terms of this Agreement.

2.2 Licenses to Greenfield.

(a) **License Grant to Greenfield.** Subject to the terms and conditions of this Agreement, Technology Partner hereby grants to Greenfield an exclusive (subject to Section 2.3), [redacted] license, with the right to grant sublicenses solely as permitted under Section 2.2(b), under the Technology Partner Technology, solely to Develop, register, use, research, reproduce, modify, and make derivatives of Products for use in the Field and in and for the Territory in accordance with and to carry out activities under this Agreement and the Development Plan.

(b) **Sublicense Rights.** Greenfield may grant sublicenses of the licenses granted in Section 2.2(a) only to (i) its Affiliates, *provided* that any such sublicense automatically terminates if such person, corporation, partnership or entity ceases to be an Affiliate of Greenfield, (ii) Third Party subcontractors for the sole purpose of performing part of Greenfield's obligations under this Agreement, (iii) any not-for-profit Third Party or Governmental Authority and (iv) any other Third Party with the prior written consent of Technology Partner, such consent not to be unreasonably withheld. Any and all sublicenses with a Sublicensee shall be subject to the following requirements (x) Greenfield shall be responsible for each of its Sublicensees' compliance with the terms hereof and shall remain responsible for all of its obligations hereunder and (y) each sublicense agreement with a Sublicensee granted after the Effective Date shall (1) be in writing, and (2) be subject to and materially consistent with the terms of this Agreement.

2.3 Retained Rights.

(a) From and after the Effective Date, notwithstanding the exclusive license granted by Greenfield to Technology Partner under Section 2.1(a), Greenfield and its Affiliates shall retain the right to (i) exercise Greenfield's rights and perform Greenfield's obligations under this Agreement, the Supply Agreement (if executed) or any related written agreement between the Parties and (ii) comply with Greenfield's obligations under applicable Law. For clarity, all rights not expressly granted herein by Greenfield are retained by Greenfield, and accordingly, subject to Section 2.5 and Section 2.6, notwithstanding any other provision to the contrary herein, Greenfield retains all rights under all Greenfield Technology to exploit Greenfield Technology (1) outside of the Field, (2) outside of the Territory, and/or (3) in connection with any product other than the Product.

(b) From and after the Effective Date, notwithstanding the exclusive license granted by Technology Partner to Greenfield under Section 2.2(a), Technology Partner and its Affiliates shall retain the right to (i) exercise Technology Partner's rights and perform Technology Partner's obligations under this Agreement, the Supply Agreement (if executed) or any related written agreement between the Parties and (ii) comply with Technology Partner's obligations under applicable Law. For clarity, all rights not expressly granted herein by Technology Partner are retained by Technology Partner, and accordingly, subject to Section 2.5, notwithstanding any other provision to the contrary herein, Technology Partner retains all rights under all Technology Partner Technology to exploit Technology Partner Technology (1) outside of the Field, (2) outside of the Territory, and/or (3) in connection with any product other than the Product.

2.4 Negative Covenant.

(a) Technology Partner will not, and will not permit any of its Affiliates or Sublicensees to, use or practice any Greenfield Technology outside the scope of the licenses granted to it under Sections 2.1(a) and 2.1(b).

(b) Greenfield will not, and will not permit any of its Affiliates or Sublicensees to, use or practice any Technology Partner Technology outside the scope of the licenses granted to it under Sections 2.2(a) and 2.2(b).

2.5 Exclusivity Covenant. [redacted]

[redacted]

2.6 Right of First Negotiation.

(a) If Greenfield determines to (i) Develop, register, manufacture, have manufactured, import, export, market, Distribute or sell, or otherwise exploit [redacted], or (ii) collaborate with, license, enable, or otherwise authorize or grant any right or enabling covenant not-to-sue to, any Third Party to do any of the foregoing in clause (i), Greenfield shall provide written notice of such determination to Technology Partner, together with any relevant data and information as may be reasonably necessary to allow Technology Partner to assess such opportunity (each, a "**ROFN Notice**"). For a period of [redacted] following receipt of a ROFN Notice, Technology Partner shall have the exclusive right to enter into good faith negotiations with Greenfield (the "**Negotiation Period**") to amend this Agreement [redacted].

(b) If the Parties do not reach agreement on amending this Agreement pursuant to Section 2.6(a) during the Negotiation Period, then Greenfield shall be permitted to discuss with a Third Party the subject matter of the ROFN Notice; *provided* that, if Technology Partner made a bona fide offer containing specific terms during the Negotiation Period but the Parties were unable to agree to amend this Agreement pursuant to Section 2.6(a) during the Negotiation Period, then Greenfield shall not be permitted, during the [redacted] period following expiration of the Negotiation Period, to enter into any agreement with a Third Party for rights [redacted] on financial terms the same as or more favorable to the Third Party than the financial terms last offered in writing by Technology Partner to Greenfield.

2.7 No Implied Licenses. Except as explicitly set forth in this Agreement, neither Party may be deemed by estoppel or implication to have granted the other Party any license, covenant or other right to any intellectual property of such Party.

ARTICLE 3
GOVERNANCE

3.1 Project Leaders.

(a) **Appointment**. Within thirty (30) days following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) a representative of such Party having a general understanding of pharmaceutical development, regulatory and commercialization issues sufficient to act as its project leader under this Agreement (each an "**Project Leader**"). Each Party may replace its Project Leader at any time by written notice to the other Party.

(b) **Specific Responsibilities**. The Project Leaders will serve as the primary administrative contact point between the Parties for the activities under this Agreement for the purpose of providing each Party with information on the Development and Regulatory Approval of Product in the Field and in the Territory and shall have the following responsibilities:

(i) facilitate the flow of information and otherwise promote communication, coordination and collaboration between the Parties;

(ii) coordinate the various functional representatives of each Party, as appropriate, in developing and executing strategies and plans;

(iii) assist the integration of teams across functional areas;

(iv) assist the Development Committee in identifying and raising cross-Party or cross-functional disputes in a timely manner; and

(v) perform such other functions as agreed by the Parties.

3.2 Development Committee.

(a) **Formation and Role.** Within thirty (30) days after the Effective Date, the Parties will establish a development committee (the "**Development Committee**") to oversee the Program. The role of the Development Committee is:

(i) to review and discuss the overall strategy for the Development of Product in the Field and in the Territory;

(ii) to monitor the Development of Product in the Field and in the Territory, including by reviewing Development Reports and the progress of Development activities;

(iii) to update the Target Date from time-to-time as appropriate;

(iv) to review and discuss any deviations or amendments to the Development Plan;

(v) to review and discuss the overall performance of the Parties pursuant to this Agreement and to compare such performance to the objectives outlined in the Development Plan; and

(vi) to perform such other functions as appropriate to further the purposes of this Agreement, as expressly set forth in this Agreement or as mutually determined by the Parties in writing.

The Development Committee has only the powers expressly assigned to it in this Section 3.2 and elsewhere in this Agreement. The Development Committee is a deliberative body with no decision-making authority; it has no power to interpret, amend, modify, or waive compliance with this Agreement. The Development Committee members will discharge their responsibilities in good faith and in a timely manner, and any consent requested by one Party of the other Party, except for any consents made pursuant to Sections 13.5 or 13.11 (which consents will be made in a Party's sole discretion) or as otherwise expressly set forth herein, will not be unreasonably withheld, conditioned or delayed.

(b) **Members.** Each Party will initially appoint two (2) representatives to the Development Committee, one of whom will be such Party's Project Leader, which representatives shall have appropriate corporate seniority, technical credentials, experience and knowledge, and ongoing familiarity with the subject matter of the Development Plan and shall be duly authorized under their respective company's internal governance procedures to carry out the powers assigned to them under this Agreement. The Development Committee may change its size from time to time by mutual written consent of the Parties and each Party may replace its representatives at any time upon written notice to the other Party; *provided*, *however*, that the Development Committee will at all times consist of equal numbers of members appointed by each Party. If a Development Committee representative from either Party is unable to attend or participate in a meeting of the Development Committee, the Party who designated such representative may designate an appropriately qualified substitute representative for the meeting.

(c) **Meetings.** The Development Committee will meet at least once every calendar quarter until the first Regulatory Approval in the Territory, and thereafter, on an as-needed basis as requested by either Party in writing, unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the Development Committee (by videoconference or teleconference) upon at least ten (10) Business Days' prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed before the next regularly scheduled meeting, and such Party will provide the Development Committee no later than five (5) Business Days before the special meeting with materials reasonably adequate to enable an informed discussion. The Development Committee may meet in person, by videoconference or by teleconference. Each Party will pay for its own expenses relating to such meetings. As appropriate, other employee representatives or agents of the Parties may attend Development Committee meetings as observers or presenters.

(d) **No Compensation**. No compensation will be paid to any of the members of the Development Committee in respect of their service as Development Committee members. Any out-of-pocket expenses incurred by the Development Committee members in performing the Development Committee's duties hereunder will be the responsibility of the Party appointing such member.

ARTICLE 4
PRODUCT DEVELOPMENT AND REGULATORY MATTERS

4.1 Overview. The Parties desire and intend to collaborate with respect to the Development of Product in the Field and in the Territory, as and to the extent set forth in this Agreement and as outlined in the Development Plan.

4.2 Development Plan.

(a) **General.** Subject to the provisions of this Agreement, each Party will use Commercially Reasonable Efforts to Develop Product pursuant to a written development plan, updated from time to time in accordance with Section 4.2(c) (the "**Development Plan**") that specifies all Development activities for Product in the Field and in the Territory.

(b) **Initial Development Plan.** As of the Effective Date, the Parties have agreed upon an initial Development Plan, which is set forth as Exhibit A hereto, and which may be updated from time to time in accordance with Section 4.2(c).

(c) **Amendments.** The Development Committee will periodically (or at the request of one of the Parties) review the then-current Development Plan, and if the Development Committee determines an amendment is needed to the then-current Development Plan, the Development Committee will collaborate to prepare an amendment to the then-current Development Plan, for review, comment and approval by each of Technology Partner and Greenfield. Such amended Development Plan will reflect any changes (including additions) to the Development of Product in the Field and in the Territory. Once approved in accordance with the foregoing, the amended Development Plan will become effective and supersede the previous Development Plan as of the date of such approval. [redacted]

(d) **Performance.** Each Party will use Commercially Reasonable Efforts to conduct the Development activities allocated to such Party in the Development Plan in a timely and effective manner with the goal of completing the Development activities under the Program by the Target Date. Notwithstanding the foregoing, neither Party makes any warranty or representation regarding its ability to achieve any particular Development objective or result and both Parties acknowledge and agree that failure to complete the Development activities under the Program by the Target Date shall not be dispositive of a Party's failure to use its Commercially Reasonable Efforts; *provided* that nothing herein shall limit each Party's obligations to use Commercially Reasonable Efforts to conduct the Development activities allocated to such Party in the Development Plan. Each Party will conduct its activities in connection with the Program in a good scientific manner and comply in all material respects with all applicable Laws.

4.3 Subcontractors. Technology Partner shall be permitted to appoint Third Party subcontractors ("**Technology Partner Subcontractors**") for the sole purpose of performing part of Technology Partner's obligations under this Agreement, [redacted] (an "**Alternative Technology Partner Subcontractor**"). Technology Partner shall be responsible for the compliance by each Technology Partner Subcontractor with the terms hereof and Technology Partner shall remain responsible for all of its obligations hereunder; *provided*, that Greenfield shall be liable in accordance with Section 9.1 for any Claims resulting from the performance (or non-performance) of any Alternative Technology Partner Subcontractor. Without limiting the foregoing, the Parties acknowledge and agree that Third Party subcontractors set forth on Exhibit E are pre-approved by Greenfield as Technology Partner Subcontractors.

4.4 Development Costs.

(a) **Development Fees.** Greenfield hereby agrees to pay Technology Partner the agreed-upon fees in consideration of Technology Partner's Development activities under the Program, as set forth in a development budget set forth on Exhibit A, or as otherwise mutually agreed upon between the Parties in writing, until the first Regulatory Approval in the Territory ("**Development Fees**"). Greenfield will pay the Development Fees in accordance with the payment schedule set forth on Exhibit A, or as otherwise mutually agreed upon between the Parties in writing. [redacted] Technology Partner will not be required to conduct any activities in respect of the Program that are not covered in the then-current Development Fees, unless and until the Parties amend the Development Plan and Development Fees therein by mutual written agreement.

(b) **Costs and Expenses.** Each Party shall be responsible for its own costs and expenses incurred in carrying out its Development activities under the Program, unless otherwise mutually agreed to in writing. For clarity, Greenfield shall be responsible for payment to Technology Partner of the Development Fees (as defined above).

(c) **Payment of Fees.** Prior to initiation of Development activities by Technology Partner, Greenfield shall pay Technology Partner a retainer of [redacted] ("**Retainer**"). Greenfield shall pay the full balance of each Development Fee invoice in United States Dollars within [redacted] of receipt of Technology Partner's invoice. If any such Development Fee invoice is not paid within such [redacted] period, Technology Partner shall be entitled to draw upon the Retainer, and Greenfield shall be obligated to refresh such Retainer to maintain a balance of [redacted]. In addition, for any anticipated payments in excess of [redacted] needed to be made by Technology Partner to any Third Parties (including subcontractors) for Development activities, Greenfield shall pay half of any such anticipated payments in advance. [redacted]

4.5 Material Data. Greenfield will use Commercially Reasonable Efforts to provide Technology Partner with all material data pertaining to the safety and efficacy of the Licensed Compound in the Program and other information reasonably necessary for the Development of the Licensed Compound and Pre-Filled Syringe in existence as of the Effective Date.

4.6 Development Reports. Each Party will provide the Development Committee with written reports summarizing the progress or results of its Development activities ("**Development Report(s)**") made since the previous Development Report at least ten (10) Business Days in advance of each regularly scheduled Development Committee meeting. The Parties will discuss the status, progress and results of the Parties' Development activities under the Program at such regularly scheduled Development Committee meetings.

4.7 Development Records. Each Party will maintain complete, current and accurate records of all Development activities under the Program, and all data and other Information resulting from such activities for a period of three (3) years after the completion of the applicable Development activity or for such longer period as is required by applicable Law. At the end of such period, each Party will provide the other Party with ninety (90) days' written notice of its intent to destroy such records, and the other Party may review and copy such records at its sole cost and expense at reasonable times, and upon reasonable notice, within such ninety (90) day period. Such records will fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory and Patent purposes. Each Party will document all of its non-Clinical Studies and Clinical Studies in formal written study records according to applicable Laws, including applicable guidelines such as ICH, GCP and GLP. Each Party may review and copy records maintained by the other Party at its sole cost and expense at reasonable times, and upon reasonable notice, obtain access to the such records.

4.8 Compliance with Laws. Each Party will conduct its activities under this Agreement in a good scientific manner and comply in all material respects with all applicable Laws, including applicable guidelines such as ICH, GCP and GLP. Each Party will secure and maintain in good order, at its own cost and expense, all current governmental registrations, licenses and permits as are required by Regulatory Authorities with jurisdiction in the Territory to perform all of its obligations under this Agreement, including manufacturing medical devices, drugs, or other components of Product, as applicable, at its facilities or at the facilities of its approved suppliers.

4.9 Regulatory Matters.

(a) **Responsibility.** Greenfield will, at Greenfield's cost, be responsible for preparing the New Drug Applications for Product (including the setting of the overall regulatory strategy therefor), other Regulatory Approvals, and other submissions to Regulatory Authorities, in accordance with the Development Plan or as otherwise approved by the Development Committee. Technology Partner will assist and cooperate with Greenfield in connection with the preparation of such Regulatory Approvals and submissions with respect to those portions of the Development activities allocated to Technology Partner under the Program, including by providing all reasonable support required relating to the Auto Injector and the chemistry, manufacturing and controls (CMC) sections of the New Drug Application for Product, in eCTD format or ready to file format for the New Drug Application, as reasonably requested by Greenfield. Technology Partner will provide Greenfield, for review and comment, all draft Regulatory Materials related to the Development activities allocated to Technology Partner under the Program, except for Regulatory Materials in Technology Partner's MAF, [redacted] in advance of the intended date of submission to a Regulatory Authority in the Territory. Technology Partner shall provide Greenfield authorizations to reference its DHF/MAF in accordance with Section 4.9(b). Greenfield will be solely responsible for submitting and maintaining New Drug Applications for Product, other Regulatory Approvals, and other submissions to Regulatory Authorities, as the sole owner thereof, and shall be solely responsible for all costs and expenses related thereto. Greenfield will also be responsible for conducting communications with Regulatory Authorities with respect to Products (including filings of or with respect to INDs, as the sole owner thereof, and other filings or communications

with Regulatory Authorities) in the Territory, in each case in accordance with the terms of this Agreement and the Development Plan. Technology Partner will assist and cooperate with Greenfield in connection with the filing of such Regulatory Approvals and submissions, as reasonably requested by Greenfield.

(b) **MAF/DHF.** Technology Partner owns MAF/DHF as it relates to the Auto Injector. Greenfield owns or has a right of reference to the DMF as it relates to the Licensed Compound and Pre-Filled Syringe, and the DHF as it relates to Product as a Combination Product, as that term is defined under 21 CFR 3.2(e). Technology Partner shall, in accordance with all applicable Laws, maintain with the FDA a MAF/DHF for the Auto Injector. Greenfield shall, in accordance with all applicable Laws, create and maintain with the FDA a DMF and a DHF for Product. Greenfield shall be entitled to cross-reference the MAF/DHF for the Auto Injector for purposes of its Regulatory Approval application review for Product and any related maintenance of the Regulatory Approval. At an appropriate time, Greenfield shall request such cross-reference letter of authorization in writing to Technology Partner, which should include all necessary information required for Technology Partner to complete such request.

(c) **Access to Auto Injector MAF/DHF.** Subject to the confidentiality provisions contained herein and additional reasonable confidentiality stipulations if requested by Technology Partner, Technology Partner shall provide to Greenfield a right to reference Technology Partner's MAF and DHF applicable to the Auto Injector in connection with any registration or approval process for Product in the Territory and any related maintenance of the Regulatory Approval to provide reference to Auto Injector information by cross-reference for review of Greenfield's New Drug Application, subject, in each such case, to Greenfield's prior notice to Technology Partner of its intention to file a New Drug Application for Product for the FDA to allow Technology Partner to make the appropriate MAF/DHF filing.

(d) **Pre-Filled Syringe DMF and Product DHF.** Greenfield shall, in accordance with all applicable Laws, and as sole owner thereof, ensure creation and maintenance of a DMF with the FDA for the Licensed Compound and Pre-Filled Syringe and a DHF for Product. Subject to the confidentiality provisions contained herein and additional reasonable confidentiality stipulations if requested by Greenfield, Greenfield shall provide Technology Partner with information from the DMF and DHF for the Product as necessary for Technology Partner to perform its obligations in connection with the Program.

(e) **Filing of a New Drug Application**. After the completion of Development activities under the Program, Greenfield shall use Commercially Reasonable Efforts to submit the New Drug Application for the Product to the FDA.

(f) **Advisory Committee Meetings.** Greenfield shall be responsible for preparing for, leading, and executing any Advisory Committee Meetings for Product, including being responsible for the costs thereof.

(g) **Regulatory Updates.**

(i) Greenfield will keep Technology Partner informed of material regulatory developments relating to Product in the Field and in the Territory through regular

reports at the Development Committee meetings and will promptly notify Technology Partner in writing of any material action or decision by the FDA relating to Product. Greenfield will promptly notify Technology Partner of any material Regulatory Materials submitted to or received from the FDA and will provide Technology Partner with copies thereof within five (5) Business Days after submission or receipt.

(ii) Technology Partner will keep Greenfield informed of material regulatory developments relating to the Auto Injector that impacts upon the Product in the Territory through regular reports at the Development Committee meetings and will promptly notify Greenfield in writing of any material action or decision by the FDA relating to the Auto Injector that impacts upon the Product.

(h) **Notification of Threatened Action.** Each Party will immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any Third Party, including a Regulatory Authority, which may affect the Development, Distribution or regulatory status of Product. Upon receipt of such information, the Parties will consult with each other to arrive at a mutually acceptable procedure for taking appropriate action.

4.10 Pharmacovigilance. To ensure compliance with timely reporting of an adverse experience or event, the safety units from each of the Parties shall meet and agree upon a written agreement for exchanging adverse experience or event and other safety information relating to the Product ("**Pharmacovigilance Agreement**") prior to Greenfield's initiation of any clinical or marketing activity for the Product in the Territory. The Pharmacovigilance Agreement shall ensure that all adverse experiences or events, or an Auto Injector incident/near incident and other safety information is exchanged according to a schedule that will permit each Party to comply with applicable Law. Upon execution of the Pharmacovigilance Agreement, it shall be attached to this Agreement as Exhibit B and shall become an integral part hereof.

ARTICLE 5
COMPENSATION

5.1 Technology Payment. In partial consideration of the Development activities to be performed by Technology Partner hereunder, Greenfield will pay to Technology Partner a one-time upfront technology payment of [redacted] within ten (10) Business Days after the Effective Date.

5.2 Milestone Payments. In addition to the payment set forth in Section 5.1, Greenfield will pay the following one-time, non-refundable milestone payments to Technology Partner, each within [redacted] after the first achievement of each milestone event (each, a "**Milestone**") indicated below:

	Milestone Event	Milestone Payment
1.	Upon [redacted]	[redacted]

	Milestone Event	Milestone Payment
2.	Upon [redacted]	[redacted]
3.	Upon [redacted]	[redacted]

The Milestone payments set forth in this Section 5.2 are payable only once, the first time the Milestone event is achieved. For clarity, this means that the total maximum amount of Milestone payments payable under this Section 5.2 is [redacted].

5.3 Payment Method. Each Party will make all payments due under this Agreement in Dollars by wire transfer of immediately available funds into an account designated by the Party that is owed such payment.

5.4 Records. Each Party will keep (and will ensure that its Affiliates, in the case of Technology Partner, and its Subsidiaries, in the case of Greenfield, and in each case, their Sublicensees keep) such records as are required to determine, in accordance with U.S. generally accepted accounting principles and this Agreement, the sums or credits due under this Agreement. Such Party will retain all such books, records and accounts until the later of (a) [redacted] after the end of the period to which such books, records and accounts pertain and (b) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by applicable Laws.

5.5 Audits. Each Party may have an independent certified public accountant, reasonably acceptable to the audited Party and subject to confidentiality obligations no less protective than those in Article 10, have access during normal business hours, and upon reasonable prior written notice, to examine only those records of the audited Party (and its Affiliates, in the case of Technology Partner, and Subsidiaries, in the case of Greenfield, and in each case, their Sublicensees) as may be reasonably necessary to determine, with respect to any Calendar Year ending not more than [redacted] before such Party's request, the correctness or completeness of any report or payment made under this Agreement. The foregoing right of review may be exercised only once per year absent error and only once with respect to each such periodic report and payment. Reports of the results of any such examination will be (a) limited to details of any discrepancies in the audited Party's records relating to Product together with an explanation of the discrepancy and the circumstances giving rise to the discrepancy, (b) made available to both Parties and (c) subject to Article 10 (and such reports and any other information received by a Party pursuant to this Section 5.5 will be deemed to be Confidential Information of the audited Party). If the audit report concludes that (i) additional amounts were owed by the audited Party, the audited Party will pay the additional amounts, with interest (at the per annum rate of the then-current prime rate as reported in The Wall Street Journal plus [redacted] or the maximum rate allowable by applicable

Law, whichever is lower) from the date originally due as provided in Section 5.3 or (ii) excess payments were made by the audited Party, the auditing Party will reimburse such excess payments, with interest (at the per annum rate of the then-current prime rate as reported in The Wall Street Journal plus [redacted] or the maximum rate allowable by applicable Law, whichever is lower) from the date when the original payment was made, in either case ((i) or (ii)), within [redacted] after the date on which such audit report is delivered to both Parties. The Party requesting the audit will bear the full cost of the performance of any such audit, unless such audit, which covers the entire Calendar Year, discloses a variance to the detriment of the auditing Party of more than [redacted] from the amount of the original report or payment calculation, in which case the audited Party will bear the full cost of the performance of such audit. The results of such audit will be final, absent manifest error. No auditor engaged in any audits under this Section 5.5 may be paid on a contingency basis.

5.6 Taxes.

(a) **Taxes on Income.** Subject to Section 5.6(d), each Party will pay and be responsible for its own income and similar taxes (including related interest and penalties) imposed on it in connection with this Agreement, including as a result of the accrual, receipt or deemed receipt of any payment by, such Party under this Agreement.

(b) **Tax Withholding.** If any taxes (including related interest and penalties) are required to be withheld by a Party with respect to an amount payable to the other Party, such Party will: (a) withhold such taxes from the payment made to the other Party; (b) timely pay the withheld taxes to the proper taxing authority; (c) send proof of payment to the other Party; and (d) reasonably assist the other Party in its efforts to obtain a refund of or credit for such tax payment in accordance with Section 5.6(c). Subject to Section 5.6(d), any amount actually withheld and remitted by a Party to a taxing authority pursuant to this Section 5.6(b) will be treated for all purposes of this Agreement as paid to the other Party. No amount shall be withheld, or a reduced amount shall be withheld, as applicable, if, in accordance with Section 5.6(c), a Party that is entitled to a payment timely furnishes the other Party with the necessary tax forms and other documents prescribed by applicable Laws, which shall be in a form reasonably satisfactory to the Party receiving the documents, identifying that the relevant payment is exempt from tax or subject to a reduced tax rate.

(c) **Tax Cooperation.** The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of payments made by one Party to the other Party under this Agreement. The Party entitled to a payment will (i) provide the paying Party with any tax forms that are reasonably necessary in order for the paying Party not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty, and (ii) notify the paying Party promptly in writing if any tax form that was previously delivered ceases to be accurate or complete. Each Party will provide the other with reasonable assistance to enable the recovery, as permitted by applicable Law, of withholding taxes, value added taxes ("**VAT**"), or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT.

(d) **Tax Actions.** Notwithstanding anything in this Agreement to the contrary, if (i) an action (including but not limited to any assignment pursuant to Section 13.5 or otherwise)

or sublicense of its rights or obligations under this Agreement, or any failure to comply with applicable Laws or filing or record retention requirements) by a payor leads to the imposition of withholding tax liability or VAT liability with respect to a payment made to the payee that would not have been imposed in the absence of such action or an increase in such liability above the liability that would have been imposed in the absence of such action, and (ii) the payee is a U.S. person (as determined for U.S. federal income tax purposes) receiving such payment in the United States, then the sum payable by the payor shall be increased (A) with respect to a VAT liability by the amount of additional VAT liability imposed and (B) with respect to the imposition of withholding tax liability to the extent necessary to ensure that the other Party receives a sum equal to the sum which it would have received had no such action occurred, reduced by any actual reduction in taxes payable by the other Party for the taxable year the other Party takes the associated payment(s) into account for tax purposes as a result of any foreign tax credits arising from such withholding tax (or any deductions in lieu of such foreign tax credits) as determined by the other Party in good faith on a "with and without" basis.

ARTICLE 6
CLINICAL DEVELOPMENT AND PRODUCT MANUFACTURING AND QUALITY

6.1 Clinical Studies. Greenfield shall be responsible for all clinical Development and Greenfield shall:

(a) not initiate any Clinical Study in the Territory until all necessary authorizations and approvals from the FDA have been obtained including authorizations under the IND, as applicable;

(b) obtain approval of applicable protocols, any informed consent form relating to Clinical Studies for Product, if any, by the appropriate Regulatory Authorities having jurisdiction in the Territory such as the Institutional Review Board or Independent Ethics Committee, prior to beginning such Clinical Studies, and shall further be responsible for preparing all reports related to obtaining any and all required approvals from the appropriate Regulatory Authorities having jurisdiction in the Territory; and

(c) obtain a signed informed consent from each subject which complies with all applicable Laws in advance of any Clinical Study participation in and for the Territory, as well as upon the receipt of any significant new findings that may impact a subject's willingness to continue clinical Development participation.

6.2 Supply of Clinical Product and Product Use. Technology Partner shall provide Product for use in connection with Clinical Studies that conforms to the Product specifications mutually agreed by the Parties in writing (the "**Product Specifications**") for Greenfield's use in accordance with the delivery schedule as set forth in the Development Plan. Greenfield shall issue purchase orders consistent with the Development Plan. The pricing for Product for use in connection with Clinical Studies shall be as set forth in Exhibit A. Quantities and lead times for supply of Product for clinical use shall be as mutually agreed by the Parties. Greenfield agrees to use such supplied units of Product solely for use in connection with Clinical Studies and in accordance with the terms and conditions of this Agreement.

6.3 Testing and Final Release of Product by Greenfield. Upon receipt of each shipment of Product for use in connection with Clinical Studies, Greenfield will examine and/or test the Product consistent with the quality control test methods agreed by the Parties in the Quality Agreement and Greenfield shall notify Technology Partner of any Defective Product in any shipment not later than (a) [redacted] after receipt of the shipment by Greenfield, for any Defect that has been discovered within this period by Greenfield via visual inspection of Product ("**Apparent Defects**"); [redacted]. Greenfield shall be responsible for final release of Product for use in connection with Clinical Studies.

6.4 Rejection; Replacement. The Parties agree to consult with each other in order to resolve any issues regarding Defective Products.

(a) [redacted]

(b) [redacted]

6.5 Dispute Resolution. [redacted]

6.6 Quality Management System. Each Party shall maintain a quality management system, a quality assurance, quality procedures and change control procedures sufficient to comply with applicable Law in the Territory. Each Party will advise the other Party of major changes to such systems and procedures that could have a materially adverse impact on the Development and commercial launch of Product.

6.7 Quality Agreement. Prior to any GMP manufacture of Product, the Parties will negotiate in good faith a quality agreement that will govern the terms and conditions of raw materials acceptance, handling and testing, and the manufacture, testing, release and acceptance of Product for use in connection with Clinical Studies under this Agreement ("**Quality**

Agreement"). Upon execution of the Quality Agreement, it shall be attached to this Agreement as Exhibit C and shall become an integral part hereof.

6.8 Inspection and Audit Rights.

(a) [redacted] each Calendar Year, Greenfield shall have the right to inspect and audit Technology Partner's facilities (subject to the terms and conditions in this Section 6.8(a)) to assure compliance with this Agreement and the Quality Agreement. In addition, Greenfield shall have the right to conduct "for cause" inspections and audits that focus on the cause(s) of a specific quality problem regarding the Development Plan or the manufacture of Product as necessary in Greenfield's sole discretion. Greenfield shall give Technology Partner reasonable prior written notice of each such inspection and audit and shall in any event in good faith attempt to advise Technology Partner in writing at least [redacted] in advance of the names of the representatives, the inspection agenda and shall provide its representatives to perform the inspection and audit with proper identification. Each inspection and audit of Technology Partner shall be during normal business hours, of reasonable duration, and shall be subject to any additional confidentiality provisions mutually agreed to and executed by Technology Partner and Greenfield in respect to such inspection and audit. Each Party shall be responsible for the expenses of its representatives in connection with such inspections and audits.

(b) [redacted]

ARTICLE 7
INTELLECTUAL PROPERTY MATTERS

7.1 Ownership of Inventions.

(a) **Greenfield Intellectual Property.** [redacted]

[redacted]

(b) **Technology Partner Intellectual Property.** [redacted]

(c) **United States Law.** The determination of whether inventions, whether or not patentable, are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for the purposes of this Agreement, be made in accordance with applicable Law in the U.S. Each Party shall, and does hereby, assign, and shall cause its Affiliates, in the case of Technology Partner, and Subsidiaries in the case of Greenfield, and their sub(licensees) and Sublicensees to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Information and other inventions, whether or not patentable, as well as any intellectual property rights with respect thereto, as necessary to fully effect the ownership provided for in Section 7.1(a) and Section 7.1(b).

(d) **Assignment Obligation**. Each Party shall cause all persons who perform Development activities or regulatory activities for such Party under this Agreement or who conceive, discover, develop or otherwise make any Information or other inventions, whether or not patentable, by or on behalf of either Party or its Affiliates, in the case of Technology Partner, and Subsidiaries in the case of Greenfield, or its or their (sub)licensees (or Sublicensees) under or in connection with this Agreement to be under an obligation to assign their rights in any Information and inventions, whether or not patentable, resulting therefrom to such Party, except where applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case, a suitable exclusive license or right to obtain such an exclusive license, shall be obtained).

7.2 [redacted]

7.3 [redacted]

7.4 Prosecution of Patents. Greenfield shall have the sole right, but not the obligation to prepare, file, prosecute and maintain the Greenfield Patents. Technology Partner shall have the sole right, but not the obligation to prepare, file, prosecute and maintain the Technology Partner Patents. Each Party will bear and be solely responsible for all costs incurred after the Effective Date in connection with the preparation, filing, prosecution or maintenance of any of its Patents that it chooses to prepare, file, prosecute or maintain in the Territory. Before any substantive prosecution filing, each Party will provide the other Party with a reasonable opportunity to review and comment on such prosecution efforts regarding the Greenfield Patents or Technology Partner Patents, as applicable, as follows: the prosecuting Party will promptly provide the other Party with copies of all material communications from any patent authority regarding such patents and shall provide the other Party, for its review and comment, with drafts of any material filings or responses to be made to such patent authorities in a reasonable amount of time in advance of submitting such filings or responses. The prosecuting Party shall consider in good faith any reasonable comments thereto provided by the other Party in connection with such prosecution. Each Party will provide the other Party all reasonable assistance and cooperation in its Patent prosecution efforts provided in this Section 7.4, including executing any other required documents or instruments for such filings and prosecution.

7.5 Patent Enforcement.

(a) **Notification.** If either Party becomes aware of any existing or threatened infringement of any of the Greenfield Patents or the Technology Partner Patents in the Field anywhere in the Territory by a Third Party ("**Territory Infringement**"), such Party will promptly notify the other Party in writing to that effect and the Parties will consult with each other regarding any actions to be taken with respect to such Territory Infringement.

(b) **Enforcement Rights.** For any Territory Infringement, each Party will share with the other Party all Information available to it regarding such actual or alleged infringement.

(i) Greenfield shall have the right, but not the obligation, to (1) bring an appropriate suit or other action against any person or entity engaged in any such Territory Infringement which infringes any Greenfield Patent, (2) defend any such Greenfield Patent in any declaratory judgement action or other legal action or administrative proceeding brought by a Third Party which alleges invalidity, unenforceability, unpatentability, or non-infringement of such Greenfield Patent, and (3), subject to Section 7.5(d),

control settlement of such action or defense of the preceding clauses (1) and (2), each at Greenfield's cost and expense.

(ii) Technology Partner shall have the right, but not the obligation, to (1) bring an appropriate suit or other action against any person or entity engaged in any such Territory Infringement which infringes any Technology Partner Patent, (2) defend any such Technology Partner Patent in any declaratory judgement action or other legal action or administrative proceeding brought by a Third Party which alleges invalidity, unenforceability, unpatentability, or non-infringement of such Technology Partner Patent, and (3), subject to Section 7.5(d), control settlement of such action or defense of the preceding clauses (1) and (2), each at Technology Partner's cost and expense.

In each case, Technology Partner and Greenfield, as applicable, will take appropriate action to enable the other Party to commence a suit or take the actions set forth in the preceding clauses (i) and (ii); provided that for clarity, (y) Technology Partner shall have no right to commence any such suit or take any such action with respect to any Greenfield Patents as set forth in the preceding clause (i), and (z) Greenfield shall have no right to commence any such suit or take any such action with respect to any such Technology Partner Patents as set forth in the preceding clause (ii).

(c) **Collaboration.** Each Party will provide to the enforcing Party reasonable assistance in such enforcement, at such enforcing Party's request and reasonable expense, including executing all necessary and proper documents and if required to establish and maintain standing to join such action as a party plaintiff if required by applicable Law to pursue such action, *provided* that the Party so joined as a party plaintiff shall be under no obligation to participate except to the extent that such participation is required as the result of its being a named party to such action, and the enforcing Party agrees to fully indemnify, defend and hold harmless the other Party from and against all Claims (including reasonable legal fees and expenses) incurred by the other Party relating thereto. Each Party will additionally use Commercially Reasonable Efforts to have joined to such action as a party plaintiff any Third Party whose joinder is required by applicable Law to establish and maintain standing to pursue such action. The enforcing Party will keep the other Party regularly informed of the status and progress of such enforcement efforts, will reasonably consider the other Party's comments on any such efforts, and will seek consent of the other Party in any important aspects of such enforcement, including determination of litigation strategy and filing of material papers to the competent court, which consent will not be unreasonably withheld, conditioned or delayed. The non-enforcing Party may obtain separate representation in such matter by counsel of its own choice and at its own expense, but such Party will at all times cooperate fully with the enforcing Party.

(d) **Settlement.** [redacted]

[redacted]

(e) **Expenses and Recoveries.** [redacted]

7.6 Infringement of Third Party Rights. [redacted]

7.7 Technology Partner Option to Cure. [redacted]

7.8 Greenfield Option to Cure. [redacted]

ARTICLE 8
REPRESENTATIONS AND WARRANTIES; COVENANTS

8.1 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party as follows:

(a) **Existence.** As of the Effective Date, it is a partnership or corporation duly organized, validly existing, and in good standing under the Laws of the jurisdiction in which it was incorporated or formed;

(b) **Power, Authority and Binding Agreement.** As of the Effective Date, (i) it has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to enforcement of remedies under applicable bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies;

(c) **No Conflict.** The execution and delivery of this Agreement, the performance of such Party's obligations hereunder and the licenses and sublicenses to be granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of applicable Law existing as of the Effective Date; (ii) do not and will not conflict with or violate the certificate of incorporation, by-laws or other organizational documents of such Party; and (iii) do not and will not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or (x) in the case of Technology Partner, any contractual obligations of its Affiliates, and (y) in the case of Greenfield, any contractual obligations of Parent or any of its Subsidiaries, in each case, existing as of the Effective Date;

(d) **Other Rights.** Neither Party nor (x) in the case of Technology Partner, any of its Affiliates, and (y) in the case of Greenfield, Parent or any of its Subsidiaries, is a party to or otherwise bound by any oral or written contract or agreement that will result in any other person obtaining any interest in, or that would give to any other person any right to assert any claim in or with respect to, any of such Party's rights under this Agreement;

(e) **Compliance with Laws.** Each Party and (x) in the case of Technology Partner, its Affiliates, and (y) in the case of Greenfield, Parent and all of its Subsidiaries, (i) are in compliance, and shall cause its and their employees, consultants or contractors to comply, with applicable Laws, and (ii) has, and shall cause its and their employees, consultants or contractors

to have all material professional licenses, consents, authorizations, permits, and certificates as required by applicable Law for its performance of this Agreement;

(f) **No Violation.** Neither Party nor (x) in the case of Technology Partner, any of its Affiliates, and (y) in the case of Greenfield, Parent or any of its Subsidiaries, is under any obligation to any person, contractual or otherwise, that is in violation of the terms of this Agreement or that would impede the fulfillment of such Party's obligations hereunder; and

(g) **No Debarment.** As of the Effective Date, neither Party, and none of such Party's employees, consultants or contractors that work in connection with the Licensed Compound or Auto Injector, as applicable:

(i) is debarred under Section 306(a) or 306(b) of the FD&C Act or by the analogous Laws of any Regulatory Authority having jurisdiction in the Territory;

(ii) has, to such Party's Knowledge, been charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U. S. C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or pursuant to the analogous Laws of any Regulatory Authority having jurisdiction in the Territory, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority having jurisdiction in the Territory; and

(iii) is excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or has been convicted of a criminal offense that falls within the scope of 42 U. S. C. §1320a-7 but not yet excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by the FDA from participation, or otherwise ineligible to participate, in any procurement or nonprocurement programs.

8.2 Additional Representations, Warranties and Covenants of Greenfield. Greenfield and Parent each represents, warrants and covenants to Technology Partner as follows, as of the Effective Date:

(a) **Title; Encumbrances.** Collectively, Greenfield and Parent have (i) sufficient legal or beneficial title, ownership or license, free and clear from any liens, claims or encumbrances, of or to the Greenfield Technology to grant the licenses to Technology Partner as purported to be granted pursuant to this Agreement; and (ii) to Greenfield's Knowledge, no Third Party has taken any action before any patent and trademark office (or similar Governmental Authority), which would render any of the Greenfield Technology invalid or unenforceable;

(b) **Notice of Infringement or Misappropriation.** It has not received any written notice from any Third Party asserting or alleging that (i) any research, Development or manufacture of the Licensed Compound by Greenfield under the Greenfield Technology before the Effective Date infringed or misappropriated the intellectual property rights of such Third Party or (ii) the exercise of Technology Partner's rights granted under this Agreement infringes or would infringe any Third Party intellectual property rights;

(c) **No Proceeding.** There are no pending, and to Greenfield's Knowledge, no threatened, adverse actions, claims, investigations, suits or proceedings against Parent or Greenfield or any of its Subsidiaries, at law or in equity, or before or by any Governmental Authority, involving the Greenfield Technology or the Licensed Compound, nor to Greenfield's Knowledge has any such adverse action, claim, investigation, suit or proceeding been brought or threatened during the past three (3) years, in each case, which has been resolved in a manner that impairs any of Greenfield's rights in and to any such Greenfield Technology or the Licensed Compound or Pre-Filled Syringe;

(d) **No Consents.** Other than entry of the Approval Order by the Bankruptcy Court, no material authorization, consent, approval of a Third Party, nor any license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority is or will be necessary for the (i) valid execution, delivery or performance of this Agreement by Greenfield; (ii) consummation by Greenfield of the transactions contemplated hereby; or (iii) prevention of the termination of any right, privilege, license or agreement relating to the Greenfield Technology or the continuation thereof following the Effective Date, except where the failure to obtain such authorization, consent, approval of a Third Party, license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority would not impair the Program or Technology Partner's rights under this Agreement;

(e) **Access to Information.** Greenfield has allowed, and will continue to allow, Technology Partner reasonable access to all information necessary for Technology Partner to perform its obligations under this Agreement in Greenfield's possession or Control (i) containing the results of all preclinical testing of the Licensed Compound, if any; and (ii) in respect of the Greenfield Technology and the Licensed Compound; and

(f) **Regulatory Matters.** Greenfield has provided or made available, when requested by Technology Partner to conduct its due diligence review, any and all documents and communications in its possession from and to any Governmental Authority, or prepared by any Governmental Authority, related to the Licensed Compound, that may bear on the compliance with the requirements of any Governmental Authority, including any notice of inspection, inspection report, warning letter, deficiency letter, internal audit reports, relevant manufacturing and laboratories investigation reports or similar communication.

8.3 Additional Representations, Warranties and Covenants of Technology Partner. Technology Partner represents, warrants and covenants to Greenfield as follows, as of the Effective Date:

(a) **Title; Encumbrances.** It has (i) sufficient legal or beneficial title, ownership or license, free and clear from any liens, claims or encumbrances, of or to the Technology Partner Technology to grant the licenses to Greenfield as purported to be granted pursuant to this Agreement; and (ii) to Technology Partner's Knowledge, no Third Party has taken any action before any patent and trademark office (or similar Governmental Authority), which would render any of the Technology Partner Technology invalid or unenforceable;

(b) **Notice of Infringement or Misappropriation.** It has not received any written notice from any Third Party asserting or alleging that (i) any research, Development or

manufacture of the Auto Injector by Technology Partner under the Technology Partner Technology before the Effective Date infringed or misappropriated the intellectual property rights of such Third Party or (ii) the exercise of Greenfield's rights granted under this Agreement infringes or would infringe any Third Party intellectual property rights;

(c) **No Proceeding.** There are no pending, and to Technology Partner's Knowledge, no threatened, adverse actions, claims, investigations, suits or proceedings against Technology Partner or any of its Affiliates, at law or in equity, or before or by any Governmental Authority, involving the Technology Partner Technology or the Auto Injector, nor to Technology Partner's Knowledge has any such adverse action, claim, investigation, suit or proceeding been brought or threatened during the past three (3) years, in each case, which has been resolved in a manner that impairs any of Technology Partner's rights in and to any such Technology Partner Technology or the Auto Injector;

(d) **No Consents.** No material authorization, consent, approval of a Third Party, and any license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority is or will be necessary for the (i) valid execution, delivery or performance of this Agreement by Technology Partner; (ii) consummation by Technology Partner of the transactions contemplated hereby; or (iii) prevention of the termination of any right, privilege, license or agreement relating to the Technology Partner Technology or the continuation thereof following the Effective Date, except where the failure to obtain such authorization, consent, approval of a Third Party, license, permit, exemption of or filing or registration with or notification to any court or Governmental Authority would not impair the Program or Greenfield's rights under this Agreement;

(e) **Access to Information.** Technology Partner has allowed, and will continue to allow, Greenfield access to all information necessary for Greenfield to perform its obligations under this Agreement in Technology Partner's possession or control (i) containing the results of all preclinical testing of the Auto Injector, if any; and (ii) in respect of the Technology Partner Technology and Auto Injector; and

(f) **Regulatory Matters.** Technology Partner has provided or made available, when requested by Greenfield to conduct its due diligence review, any and all documents and communications in its possession from and to any Governmental Authority, or prepared by any Governmental Authority, related to the Auto Injector, that may bear on the compliance with the requirements of any Governmental Authority, including any notice of inspection, inspection report, warning letter, deficiency letter, internal audit reports, relevant manufacturing and laboratories investigation reports or similar communication. Technology Partner has also provided or made available documents supporting its submissions to FDA, including CMC Information.

8.4 Covenants.

(a) **No Debarment.** During the Term, neither Party nor Parent will be, and neither Party nor Parent will use any employee, consultant or contractor in connection with the Program who has been:

(i) debarred under Section 306(a) or 306(b) of the FD&C Act or pursuant to the analogous Laws of any Regulatory Authority having jurisdiction in the Territory;

(ii) charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U. S. C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or otherwise pursuant to the analogous Laws of any Regulatory Authority having jurisdiction in the Territory, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority having jurisdiction in the Territory, during the employee's or consultant's employment or contract term with such Party; or

(iii) excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or who has been convicted of a criminal offense that falls within the scope of 42 U. S. C. §1320a-7 but has not yet been excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by the FDA from participation, or otherwise ineligible to participate, in any procurement or nonprocurement programs.

(b) **Notice.** Each Party will notify the other Party promptly, but in no event later than five (5) Business Days, upon becoming aware that any of its, and in the case of Greenfield, including Parent's, employees, consultants or contractors working with the Program has been excluded, debarred, suspended or is otherwise ineligible, or is the subject of exclusion, debarment or suspension proceedings by the FDA.

(c) **Compliance.** Each Party and (x) in the case of Technology Partner, its Affiliates, and (y) in the case of Greenfield, Parent and all of its Subsidiaries, will comply in all material respects with all applicable Laws in such Party's Development and manufacture of Product and the performance of its obligations under this Agreement, including where applicable the statutes, regulations and written directives of the FDA and any Regulatory Authority having jurisdiction in the Territory, the FD&C Act, the Prescription Drug Marketing Act, the Federal Health Care Programs Anti-Kickback Law, 42 U. S. C. 1320a-7b(b), the statutes, regulations and written directives of Medicare, Medicaid and all other healthcare programs, as defined in 42 U. S. C. § 1320a-7b(f) and the Foreign Corrupt Practices Act of 1977, each as may be amended from time to time and each to the extent applicable.

(d) **JRA Provision.** Each Party acknowledges and agrees that:

(i) the provisions herein are intended to encompass and include a joint research agreement for the performance of experimental, developmental and research work as contemplated by 35 U.S.C. § 102(c), and that any invention made in connection with the activities contemplated in this Agreement, whether made solely by or on behalf of one Party or jointly by or on behalf of both Parties, is intended to and should have the benefit of the rights and protections conferred by 35 U.S.C. § 102(c) (the "**JRA Provision**");

(ii) in the event that a Party seeks to rely on the foregoing and invoke the JRA Provision with respect to any invention that is the subject of a Patent application filed by or on behalf of such Party, such Party will give prior written notice(s) to the other Party of its intent to invoke the JRA Provision and of each submission or disclosure such Party intends to make to any patent and trademark office (or similar Governmental Authority) pursuant to the JRA Provision, including: (A) any disclosure of or regarding the existence or contents of this Agreement to any patent and trademark office (or similar Governmental Authority); (B) the disclosure of any "subject matter developed by the other Party" (as such term is used in the JRA Provision) in, without limitation, an information disclosure statement, or (C) the filing of any terminal disclaimer over the intellectual property of the other Party, it being agreed that no such submission, disclosure or filing will be made by such Party without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed;

(iii) without limiting Section 8.4(d)(ii) above, it will not be a violation of confidentiality obligations hereunder for a Party, as necessary in connection with the invocation of the JRA Provision, to disclose to any patent and trademark office (or similar Governmental Authority) (A) the published intellectual property of the other Party in, without limitation, an information disclosure statement or (B) this Agreement, *provided* that such Party exercises reasonable efforts to limit the scope of such disclosure as strictly necessary to invoke the JRA Provision, including by reasonably redacting the material terms of this Agreement before any such disclosure; and

(iv) without limiting Section 8.4(d)(ii) above, each Party will provide reasonable cooperation to the other Party in connection with such other Party's efforts to invoke and rely on the JRA Provision.

8.5 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY, AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

8.6 Supply. Prior to the date that is [redacted] from the expected submission of a New Drug Application, the Parties will negotiate in good faith and execute a supply agreement pursuant to which Technology Partner will manufacture, or have manufactured, and supply to Greenfield Product for the Distribution of Product in the Territory (the "**Supply Agreement**"). [redacted]

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Greenfield. Greenfield will, and Parent will ensure that Greenfield will, in each case at its sole expense, defend, indemnify, and hold Technology Partner and its Affiliates and their respective officers, directors, shareholders or owners, employees, contractors, consultants, and agents (the "**Technology Partner Indemnitees**") harmless from and against any and all Third Party claims, suits, proceedings, damages, losses, liabilities, taxes, costs, expenses (including court costs and reasonable attorneys' fees and expenses) and recoveries (collectively, "**Claims**") to the extent that such Claims arise out of, are based on, or result from (a) the breach of any of Greenfield's obligations under this Agreement, including Greenfield's and Parent's representations and warranties, covenants and agreements, (b) injury or death to any person or damage to any property resulting from or caused by the (1) [redacted], (2) [redacted], (c) the negligence, recklessness or willful misconduct of Greenfield or Greenfield Indemnitees in the performance of its obligations hereunder, (d) allegations that the [redacted], or use thereof (but specifically excluding any allegations relating [redacted]) infringes (including by inducement) any Third Party intellectual property rights, or (e) the performance or non-performance of any Alternative Technology Partner Subcontractor. [redacted]

9.2 Indemnification by Technology Partner. Technology Partner will, at its sole expense, defend, indemnify, and hold Parent, Greenfield and its Subsidiaries and their respective officers, directors, shareholders or owners, employees, contractors, consultants, and agents (the "**Greenfield Indemnitees**") harmless from and against any and all Claims to the extent that such Claims arise out of, are based on, or result from (a) [redacted], (b) the breach of any of Technology Partner's obligations under this Agreement, including Technology Partner's representations and warranties, covenants and agreements, (c) injury or death to any person or damage to any property resulting from or caused by the (1) [redacted] or (2) [redacted], (d) the negligence, recklessness or willful misconduct of Technology Partner or Technology Partner Indemnitees in the performance of its obligations hereunder, (e) allegations that the [redacted], or the use thereof generally (but specifically not [redacted]) infringes (including by inducement) any Third Party intellectual property rights or (f) the performance or non-performance of any Technology Partner Subcontractor other than an

Alternative Technology Partner Subcontractor. [redacted]

9.3 Indemnification Procedures. The Party claiming indemnity under this Article 9 (the "**Indemnified Party**") will give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Claim; *provided, however*, that the failure of the Indemnified Party to provide such written notice will not release the Indemnifying Party from its obligations to the Indemnified Party under this Article 9 except to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. The Indemnified Party will provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's reasonable expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; *provided*, *however*, the Indemnifying Party may assume and conduct the defense of the Claim with counsel of its choice, which counsel will be reasonably acceptable to the Indemnified Party. The Indemnifying Party will not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party will not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided in this Article 9.

9.4 Limitation of Liability. [redacted] NEITHER PARTY NOR ANY OF ITS AFFILIATES OR SUBLICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE, REMOTE, EXEMPLARY OR SPECULATIVE DAMAGES, INCLUDING BUT NOT LIMITED TO LOST PROFITS, ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES OR THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY.

9.5 Insurance. Each Party shall maintain general liability insurance in the amounts not less than [redacted] per occurrence and [redacted] in the aggregate and products liability insurance in the amount of [redacted] per occurrence and in the aggregate, in a manner adequate to cover its obligations hereunder and consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested or commercially distributed or sold by such Party. Each Party's insurance, which may be via a self-insurance program or captive, shall be procured at its own expense.

ARTICLE 10
CONFIDENTIALITY

10.1 Confidentiality. Each Party agrees that it and its Affiliates will (y) keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as provided for in this Agreement any Confidential Information furnished to it or its Affiliates by or on behalf of the other Party or its Affiliates pursuant to this Agreement, except to the extent expressly authorized by this Agreement or as otherwise agreed to in writing by the Parties, and (z) safeguard Confidential Information of the other Party using at least the same degree of care as it holds its own Confidential Information, which in no event shall be less than a reasonable degree of care. The foregoing confidentiality and non-use obligations do not apply to any portion of the other Party's Confidential Information that the receiving Party can demonstrate by competent written proof:

(a) was already known to the receiving Party or its Affiliates, other than under an obligation of confidentiality, at the time of disclosure by the other Party or its Affiliates;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party or its Affiliates;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement;

(d) was disclosed to the receiving Party or its Affiliates by a Third Party who had a legal right to make such disclosure and who did not obtain such information directly or indirectly from the other Party or its Affiliates; or

(e) was independently discovered or developed by the receiving Party or its Affiliates without access to or aid, application or use of the other Party's Confidential Information.

10.2 Authorized Disclosure. Notwithstanding the obligations set forth in Section 10.1, a Party or its Affiliates may disclose the other Party's Confidential Information and the terms of this Agreement to the extent:

(a) such disclosure is reasonably necessary (i) for the filing or prosecuting of Patent rights as contemplated by this Agreement; (ii) to comply with the requirements of Regulatory Authorities having jurisdiction in the Territory with respect to obtaining and maintaining Regulatory Approval of Product; or (iii) for prosecuting or defending litigation as contemplated by this Agreement;

(b) such disclosure is reasonably necessary to its officers, directors, employees, agents, consultants, contractors, licensees, Sublicensees, attorneys, accountants, bankers, lenders, insurers or licensors on a need-to-know basis for the sole purpose of performing its obligations or exercising its rights under this Agreement; *provided* that in each case, the disclosees are bound by obligations of confidentiality and non-use no less stringent than those contained in this Agreement;

(c) such disclosure is reasonably necessary to any bona fide potential or actual investor, acquiror, merger partner, or other financial or commercial partner for the sole purpose of evaluating an actual or potential investment, acquisition or other business relationship; *provided* that in each case, the disclosees are bound by written obligations of confidentiality and non-use no less stringent than those contained in this Agreement;

(d) such disclosure is required to comply with applicable Laws, including regulations promulgated by any securities exchange on which a Party is listed, court order, administrative subpoena or other order; *provided* that in the event such disclosure is required by a securities exchange on which a Party is listed, such disclosure will comply with Section 10.4(c); or

(e) such disclosure is reasonably necessary for Greenfield or Parent to obtain the Approval Order or otherwise in furtherance of the confirmation of a plan of reorganization in the Chapter 11 Cases; *provided* that in each case, (i) the disclosees are subject to the terms of the Protective Order, and (ii) each of Greenfield and Parent exercises reasonable efforts to limit the scope of such disclosure for any documents filed in the Chapter 11 Cases that are expected to be generally available to the public, including by using reasonable efforts to redact the material terms of this Agreement before any such disclosure.

Notwithstanding the foregoing, if a Party or its Affiliate is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.2(a) or Section 10.2(d) such Party will promptly notify the other Party of such required disclosure and, upon the other Party's request, such Party and its Affiliates will, at the other Party's reasonable expense, use reasonable efforts to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the required disclosure. In any event, a Party or its Affiliate required to make disclosure of the other Party's Confidential Information pursuant to Section 10.2(a) or Section 10.2(d) shall disclose only that portion of Confidential Information which its legal counsel determines it is legally required to disclose.

10.3 Technical Publication. Neither Party nor their Affiliates shall submit for publication, publish or present a publication, or other form of public disclosure such as an abstract and presentation, of results of studies carried out under this Agreement or otherwise relating to Product (each of the foregoing, a "**Publication**") without the opportunity for prior review by the other Party, except to the extent required by applicable Laws. A Party seeking, or whose Affiliate is seeking, to submit, publish or present a Publication shall provide the other Party the opportunity to review and comment on the proposed Publication [redacted] before its intended submission for publication or presentation. The other Party shall provide the Party seeking, or whose Affiliate is seeking, to publish or present with its comments in writing, if any, within [redacted] after receipt of such proposed Publication. The Party seeking, or whose Affiliate is seeking, to publish or present shall consider in good faith any comments thereto provided by the

other Party and shall comply with the other Party's request to remove any and all of such other Party's Confidential Information from the proposed Publication. In addition, the Party seeking, or whose Affiliate is seeking, to publish or present shall delay the submission for a period of [redacted] if the other Party can show demonstrable need for such delay to prepare and file a patent application for which it has prosecution control pursuant to this Agreement. If the other Party fails to provide its comments to the Party seeking, or whose Affiliate is seeking, to publish or present within such [redacted] period, such other Party will be deemed not to have any comments, and the Party seeking, or whose Affiliate is seeking, to publish or present may submit for publication or present in accordance with this Section 10.3 after the [redacted] period has elapsed. The Party seeking, or whose Affiliate is seeking, to publish or present shall provide the other Party a copy of the manuscript, abstract or presentation at the time of the submission or presentation, as applicable. Greenfield shall in no event identify Technology Partner, either expressly or in sufficient detail that its identity would be apparent, in any such publication or presentation without the prior express written consent of Technology Partner, which consent may be withheld for any reason. For clarity, Technology Partner and its Affiliates may not submit, publish or present a Publication relating to Product without Greenfield's prior express written consent, and Greenfield and its Affiliates may not submit, publish or present a Publication (i) relating solely to the Auto Injector, or (ii) that includes information regarding the Auto Injector that materially varies from or is otherwise materially inconsistent with information furnished by Technology Partner to Greenfield under this Agreement, in each case without Technology Partner's prior express written consent.

10.4 Publicity; Terms of Agreement.

(a) The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth in this Section 10.4.

(b) Neither Party may make any public announcement concerning the terms and conditions of this Agreement except as may be required pursuant to Section 10.2(a) or Section 10.2(d), or make any public statement which includes the name or marks of the other Party or any of its Affiliates, or otherwise use the name or marks of the other Party or any of its Affiliates in any public statement, document, or Product except as may be required pursuant to Section 10.2(a) or Section 10.2(d), without the written consent of the other Party. Neither Party nor its Affiliates are required to seek the permission of the other Party to repeat any information regarding the terms and conditions of this Agreement that has already been publicly disclosed by such Party or its Affiliates, or by the other Party or its Affiliate, in accordance with this Section 10.4, if such information remains accurate as of such time.

(c) The Parties acknowledge that either or both Parties may be obligated to file under applicable Laws a copy of this Agreement with the U.S. Securities and Exchange Commission or other Governmental Authorities. Each Party will make such a required filing and will request confidential treatment of the commercial terms and sensitive technical or other competitively sensitive terms hereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, the filing Party will provide the other Party with a copy of this Agreement marked to show the provisions for which the filing Party intends to seek confidential treatment and will reasonably consider and incorporate the other Party's

comments thereon to the extent consistent with the legal requirements, with respect to the filing Party, governing disclosure of material agreements and material information that must be publicly filed.

10.5 Prior Confidentiality Agreements. The Confidentiality Agreement shall terminate with effect from the Effective Date and is superseded by this Agreement; *provided* that all Information disclosed by a Party or its Affiliate to the other Party or its Affiliate pursuant to any prior confidentiality agreements, including the Confidentiality Agreement, will be deemed such Party's Confidential Information disclosed hereunder and the other Party will and its Affiliates and disclosees will also have the confidentiality, non-use and non-disclosure obligations set forth in this Article 10 with respect to such Confidential Information.

10.6 Survival. The provisions of this Article 10 shall survive for a period of [redacted] after the expiration or termination of this Agreement, *provided, however* that such provisions shall survive indefinitely with respect to any Confidential Information contained in any Greenfield Know-How licensed to Technology Partner pursuant to Section 7.3 and Section 11.11.

10.7 Return of Confidential Information. Except as otherwise set forth in this Agreement, upon termination or expiration of this Agreement, the receiving Party will promptly return, or, at the disclosing Party's option, destroy, all of the disclosing Party's Confidential Information, including all reproductions and copies thereof in any medium, except that the receiving Party may retain (i) one (1) archival copy to ensure continuing compliance with this Article 10, or as may be required by applicable Law, and (ii) any computer records or files containing such Confidential Information that have been created by the receiving Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the receiving Party's standard archiving and back-up procedures, but not for any other uses or purposes.

10.8 Unauthorized Use. If either Party becomes aware or has knowledge of any unauthorized use or disclosure of the other Party's Confidential Information, it will promptly notify the other Party of such unauthorized use or disclosure and all facts known to it regarding same. For clarity, such notice shall not remedy any breach of this Agreement resulting from such unauthorized use or disclosure, and each Party shall be responsible and liable for any breach of this Article 10 by any of its disclosees.

10.9 Exclusive Property. All Confidential Information is the sole and exclusive property of the disclosing Party and the permitted use thereof by the receiving Party for purposes of its performance hereunder will not be deemed a license or other right of the receiving Party to use any such Confidential Information for any other purpose.

ARTICLE 11
EFFECTIVENESS, TERM AND TERMINATION

11.1 Effectiveness. This Agreement shall become effective and binding on the Parties on the date that this Agreement has been executed by the Parties and the Approval Order is entered by the Bankruptcy Court, and such Approval Order is not subject to any stay (such date, the "**Effective Date**").

11.2 Term. This Agreement becomes effective on the Effective Date, and, unless sooner terminated as specifically provided in this Agreement, will continue in effect for the longer of (a) the date on which all Development activities under the Program are completed, and (b) the term of the Supply Agreement (the "**Term**").

11.3 Unilateral Termination by Technology Partner. Notwithstanding any other provision of this Agreement, Technology Partner may in its sole and absolute discretion terminate this Agreement (a) [redacted] and (b) [redacted] written notice to Greenfield. [redacted]

11.4 Unilateral Termination by Greenfield. Notwithstanding any other provision of this Agreement, Greenfield may, at any time, terminate this Agreement, upon [redacted] written notice to Technology Partner, *provided* that if Greenfield elects to terminate this Agreement prior to the first Regulatory Approval in the Territory, Greenfield shall also provide a payment of an amount equal to [redacted] concurrently with the delivery of such written notice.

11.5 Termination Upon Change of Control of Greenfield. Promptly, but no later than [redacted] following the completion of any Change of Control of Greenfield pursuant to which the acquirer or merger partner or other entity gaining control of Greenfield (as the term control is defined in the definition of "Affiliate") is engaged, or has a then-existing plan to engage in the Distribution of a Competitive Product, Greenfield will provide written notice of the same to Technology Partner (a "**Greenfield Change of Control Notice**"). Within [redacted] of the effective date of such transaction, (a) Greenfield will provide a second written notice to Technology Partner setting forth whether it will (i) divest the Competing Product within such [redacted] period or (ii) terminate this Agreement with immediate effect, and (b) complete the activities in subsections (a)(i) or (a)(ii), as elected by Greenfield in such notice, within such [redacted] period; *provided* that Greenfield's Distribution of such Competing Product in the Territory during such [redacted] period if already Distributed shall not constitute a breach by Greenfield of its obligations set forth in Section 2.5. In the event that Greenfield does not provide such second written notice within such [redacted] period, Technology Partner has the right to terminate this Agreement immediately upon the expiration of such [redacted] period.

11.6 Termination for Breach. Each Party (the "**Non-Breaching Party**") may terminate this Agreement immediately upon written notice to the other Party (the "**Breaching Party**") if the Breaching Party materially breaches its obligations under this Agreement and, after receiving written notice identifying such material breach in reasonable detail (a "**Default Notice**"), fails to cure such material breach within [redacted] after delivery of the Default Notice (or within [redacted] after delivery of the Default Notice if such material breach is solely based on the Breaching Party's failure to pay any amounts due hereunder). If a Party gives notice to the Breaching Party pursuant to this Section 11.6 as a result of a material breach (or alleged material breach) by the Breaching Party and, on or before the end of the cure period therefor, either Party

has referred the matter to arbitration pursuant to Section 12.1, in either case where the Breaching Party is in good faith disputing such basis for termination pursuant to this Section 11.6, then [redacted] If the material breach is so cured within the remainder of the cure period, then this Agreement will remain in full force and effect, otherwise this Agreement will terminate. [redacted]

11.7 Termination for Debarment. Either Party shall have the right to terminate this Agreement immediately by providing written notice to the other Party if the other Party has been:

(a) debarred under Section 306(a) or 306(b) of the FD&C Act or pursuant to the analogous Laws of any Regulatory Authority having jurisdiction in the Territory;

(b) charged with, or convicted of, any felony or misdemeanor within the ambit of 42 U. S. C. §§ 1320a-7(a), 1320a-7(b)(l)-(3), or otherwise pursuant to the analogous Laws of any Regulatory Authority having jurisdiction in the Territory, or is proposed for exclusion, or the subject of exclusion or debarment proceedings by a Regulatory Authority having jurisdiction in the Territory, during the employee's or consultant's employment or contract term with such Party; or

(c) excluded, suspended or debarred from participation, or otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs (or who has been convicted of a criminal offense that falls within the scope of 42 U. S. C. §1320a-7 but has not yet been excluded, debarred, suspended, or otherwise declared ineligible), or excluded, suspended or debarred by the FDA from participation, or otherwise ineligible to participate, in any procurement or nonprocurement programs.

11.8 [redacted]

(a) [redacted]

(b) [redacted]

[redacted]

(c) [redacted]

(d) [redacted]

11.9 Effect of Termination. [redacted]

[redacted]

11.10 Survival. Termination or expiration of this Agreement will not affect rights or obligations of the Parties under this Agreement that have accrued before the date of termination or expiration. Notwithstanding anything to the contrary, the following provisions will survive any expiration or termination of this Agreement: Article 1 (Definitions), Section 2.5 (Exclusivity Covenant; for the time period specified therein), Section 4.4 (Development Costs; with respect to amounts due prior to expiration or termination), Section 4.7 (Development Records; if applicable, to the time period specified therein), Section 5.1 (Technology Payment; with respect to amounts due prior to expiration or termination), Section 5.2 (Milestone Payments; with respect to amounts due prior to expiration or termination), Section 5.3 (Payment Method), Section 5.4 (Records), Section 5.5 (Audits), Section 5.6 (Taxes), Section 7.1 (Ownership of Inventions), Article 9 (Indemnification), Article 10 (Confidentiality; for the time period specified in Section 10.6 (Survival)), Article 11 (Effectiveness, Term and Termination), Article 12 (Dispute Resolution) and Article 13 (Miscellaneous).

11.11 Step-in Rights.

(a) **Obligation Upon Step-in Notice.** Technology Partner shall have the right to issue a Step-in Notice to Greenfield anytime Technology Partner has the right to terminate this Agreement pursuant to Section 11.6 (Termination for Breach) or Section 11.7 (Termination for Debarment), or within thirty (30) days from the effective date of termination of this Agreement by Technology Partner pursuant to Section 11.6 (Termination for Breach) or Section 11.7 (Termination for Debarment). Upon Technology Partner's issuance of a Step-in Notice, (i) Greenfield shall promptly transfer to Technology Partner the Greenfield Know-How, including, data from pre-clinical development activities, data obtained through Clinical Studies, and Regulatory Materials for the Product under this Agreement, and (ii) this Agreement shall terminate, subject to any applicable notice periods remaining.

(b) **Transition Plan.** Upon Technology Partner's request, the Parties shall jointly prepare in good faith a transition plan pursuant to which Greenfield shall disclose to Technology Partner any and all Greenfield Technology. Such transition plan shall include the plan for the transfer from Greenfield to Technology Partner or its designee of all Greenfield Know-How, including documents and materials relating to, or generated from, Development, regulatory, Distribution and commercialization activities with respect to the Licensed Compound, Pre-Filled Syringe, or Product undertaken by or for Greenfield prior to the Effective Date and during the Term, such Greenfield Know-How including, with respect to the Product, data from pre-clinical development activities, data obtained through Regulatory Materials for the Product.

(c) **Step-In License.** Upon Technology Partner's request, Greenfield shall grant, and hereby grants, to Technology Partner a non-exclusive, worldwide, royalty-free license, with the right to sublicense (through multiple tiers), to use or practice the Greenfield Technology to Develop, register, use, research, reproduce, modify and make derivatives of Products for use in the Field and in the Territory and to make and have made, use, sell, offer for sale, import and export and otherwise Distribute Products in the Field and in the Territory.

(d) **Transfer of Regulatory Files.** Greenfield shall transfer to Technology Partner any Regulatory Materials and Regulatory Approvals for the Product.

(e) **Further Assurances.** Upon Technology Partner's request, Greenfield shall execute and deliver any and all instruments and documents and take such other acts as may be necessary or desirable to document the license and transfer described in this Section 11.11, and provide reasonable assistance, including making appropriate employees available to Technology Partner at reasonable times, places and frequency, for the purpose of assisting Technology Partner in exercising its rights under this Section 11.11.

ARTICLE 12
DISPUTE RESOLUTION

12.1 Arbitration. [redacted]

12.2 Equitable Relief. Notwithstanding Section 12.1, each Party acknowledges that its breach of Article 10 may cause irreparable harm to the other Party, which cannot be reasonably or adequately compensated by damages in an action at law. By reason thereof, each Party agrees that the other Party may, in addition to any other remedies it may have under this Agreement or otherwise, seek preliminary and permanent injunctive and other equitable relief from any state or federal court of competent jurisdiction in New York, New York to prevent or curtail any actual or threatened breach of Article 10 that is reasonably likely to cause it irreparable harm. In addition, notwithstanding Section 12.1, to the fullest extent provided by applicable Law, either Party may bring an action in any court of competent jurisdiction for injunctive relief (or any other provisional remedy) to protect a Party's rights or enforce a Party's obligations under this Agreement pending

final resolution of any claims related thereto pursuant to the dispute resolution procedure set forth in Section 12.1. The Parties further agree that no bond or other security shall be required in obtaining injunctive and other equitable relief.

12.3 Governing Law. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof are governed by and construed under the laws of the State of New York without giving effect to any choice of law principles that would require the application of the laws of a different state.

12.4 Patent and Trademark Disputes. Notwithstanding Section 12.1, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent or trademark rights outside the U.S. covering the manufacture, use, importation, offer for sale or sale of Product will be submitted to a court of competent jurisdiction in the country in which such Patent or trademark rights were granted or arose.

ARTICLE 13
MISCELLANEOUS

13.1 Entire Agreement; Amendment. This Agreement, including the Exhibits hereto, together with the Development Plan and any other documents delivered pursuant hereto or thereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto and thereto and their Affiliates with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties with respect to the subject matter of this Agreement other than as are set forth in this Agreement and the Development Plan. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties or Parent unless reduced to writing and signed by an authorized officer of each Party and Parent.

13.2 Force Majeure. Each Party will be excused from the performance of (and accordingly shall not be in breach of) its obligations under this Agreement to the extent that such performance is prevented by force majeure and the non-performing Party promptly provides notice of the prevention to the other Party. Such excuse will continue for so long as the condition constituting force majeure continues and the non-performing Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure includes conditions beyond the reasonable control of the Parties, including an act of God, war, civil commotion, terrorist act, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, and storm or like catastrophe. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a force majeure affecting such Party. If a force majeure persists for more than [redacted], then the Parties will discuss in good faith the modification of the Parties' obligations under this Agreement to mitigate the delays caused by such force majeure.

13.3 Notices. Any notice required or permitted to be given under this Agreement will be in writing, will specifically refer to this Agreement, and will be addressed to the appropriate

Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 13.3, and will be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by email with non-automated confirmed read receipt or a reputable courier service, or (b) five (5) Business Days after mailing, if mailed by first class certified or registered airmail, postage prepaid, return receipt requested. The recipient shall promptly confirm its receipt of any such email.

If to Greenfield:

Greenfield Bioventures L.P.
1 Stamford Forum
Stamford, CT 06901
Attn: Office of the General Counsel
Fax: (203) 588-6272
E-mail: Marc.Kesselman@pharma.com

With a copy to (which will not constitute notice):

Purdue Pharma L.P.
1 Stamford Forum
Stamford, CT 06901
Attn: Senior Vice President, Business Development

Arnold & Porter Kaye Scholer LLP
250 West 55th Street
New York, NY 10019-9710
Attn: Rory Greiss and Eric Rothman
E-mail: rory.greiss@arnoldporter.com and
eric.rothman@arnoldporter.com

If to Technology Partner:

[redacted]
Attn: [redacted]
E-mail: [redacted]

With a copy to (which will not constitute notice):

[redacted]
Attn: [redacted]
E-mail: [redacted]

13.4 No Strict Construction; Interpretation; Headings. The language in this Agreement is to be construed in all cases according to its fair meaning. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender applies to all genders. The word "or" is used in the disjunctive sense and the word

"and" is used in the conjunctive sense. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" means including, without limiting the generality of any description preceding such term. The Parties agree that no meaning should be inferred about the use of "without limitation" or "including, but not limited to" in some instances but not others. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Laws will be construed as referring to such Laws as from time to time enacted, repealed or amended, (c) any reference to any person will be construed to include the person's successors and permitted assigns, (d) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) any reference to the words "mutually agree" or "mutual written agreement" will not impose any obligation on either Party to agree to any terms relating thereto or to engage in discussions relating to such terms except as such Party may determine in such Party's sole discretion, (f) all references to Sections, Exhibits or Schedules will be construed to refer to Sections, Exhibits and Schedules to this Agreement, (g) the word "days" means calendar days unless otherwise specified, and (h) the words "copy" and "copies" and words of similar import when used in this Agreement include, to the extent available, electronic copies, files or databases containing the information, files, items, documents or materials to which such words apply. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

13.5 Assignment. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other Party, except that a Party may make such an assignment without the other Party's consent to (i) in the case of Technology Partner, its Affiliates, (ii) in the case of Greenfield, Parent or a Subsidiary, upon thirty (30) days' prior notice to Technology Partner or such shorter period as may be practicable under the circumstances, (iii) a Third Party with which such Party may merge or consolidate, (iv) a Third Party to which such Party may transfer all or substantially all of its assets (such Third Party, an "**Acquiror**", whether by way of a merger, sale of stock, sale of assets or other like transaction) and (v) in the case of Greenfield, to any not-for-profit Third Party. Any successor or assignee of rights or obligations permitted hereunder will, in writing to the other Party, expressly assume performance of such rights or obligations. Any permitted assignment will be binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 13.5 is null, void and of no legal effect. No assignment will relieve either Party of responsibility for the performance of any accrued obligation which such Party then has hereunder.

13.6 Performance by Affiliates. Each Party may discharge any obligations and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to

comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement is a breach by such Party, and the other Party may proceed directly against such Party without any obligation to first proceed against such Party's Affiliate.

13.7 Guarantee. In consideration of the rights granted to Greenfield under this Agreement, and to induce Technology Partner to enter into this Agreement, Parent, hereby irrevocably and unconditionally guarantees, in favor of Technology Partner and its Affiliates, the prompt and full performance of all of Greenfield's and its Subsidiaries' obligations under this Agreement, including indemnification obligations and the accuracy of all representations and warranties provided herein. Parent agrees to be bound by all of Greenfield's and its Subsidiaries' obligations under this Agreement and may exercise any defenses available to Greenfield and its Subsidiaries under this Agreement. Parent agrees to take such action as may be necessary to keep itself informed as to the scope and performance of such obligations and of the affairs of Greenfield and its Subsidiaries pursuant to this Agreement and agrees that Technology Partner has no obligation to notify Parent of any matter which may increase or change its obligations hereunder as a guarantor or to assist Parent in managing or supervising Greenfield or its Subsidiaries; *provided* that no amendment to this Agreement may be made without Parent's written consent. No failure or delay or lack of demand, notice or diligence in exercising any right under this Section 13.7 shall operate as a waiver thereof, nor shall any single or partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right under this Section 13.7. Subject to the provisions hereof, this guarantee is an absolute, unconditional and continuing guarantee of performance and upon Technology Partner's reasonable request Parent shall provide reasonable assurances to Technology Partner from time to time of the continuing effect hereof. Any provision of this Section 13.7 that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. Parent represents, warrants and covenants to Technology Partner that it has the corporate power and authority to enter into this guarantee, that all corporate and governmental approvals needed by it to enter into and to perform hereunder have been secured or obtained, and that the provisions of this Section 13.7 are a legal and valid obligation binding upon it and is enforceable in accordance with its terms, and that the execution hereof does not conflict with any agreement, undertaking, or instrument to which it is a party. Parent hereby expressly waives any requirement that Technology Partner exhaust any right, power or remedy against Greenfield hereunder prior to proceeding directly against Parent under this Section 13.7. For the avoidance of doubt, this Section 13.7 shall survive the termination of this Agreement. Additionally, each obligation of or reference to Greenfield in this Agreement shall be deemed to also be the obligation of or reference to Parent, unless specifically provided otherwise or implied otherwise by the context.

13.8 Third Party Beneficiary. Parent shall be an express third party beneficiary of this Agreement entitled to all of the benefits and to exercise all of the rights of Greenfield hereunder and shall be entitled to enforce the provisions of this Agreement as if it were a party hereto for all purposes.

13.9 Further Assurances and Actions. Each Party, upon the request of the other Party, whether before or after the Effective Date and without further consideration, will do, execute,

acknowledge, and deliver or cause to be done, executed, acknowledged or delivered all such further acts, deeds, documents, assignments, transfers, conveyances, powers of attorney, instruments and assurances as may be reasonably necessary to effect complete consummation of the transactions contemplated by this Agreement, and to do all such other acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement. The Parties agree to execute and deliver such other documents, certificates, agreements and other writings and to take such other actions as may be reasonably necessary to consummate or implement expeditiously the transactions contemplated by this Agreement.

13.10 Severability. Each of the provisions contained in this Agreement will be severable, and the unenforceability of one will not affect the enforceability of any others or of the remainder of this Agreement. If any one or more of the provisions of this Agreement, or the application thereof in any circumstances, is held to be invalid, illegal, or unenforceable in any respect for any reason, the Parties will negotiate in good faith with a view to the substitution therefor of a suitable and equitable solution to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid provision; *provided, however,* that the validity, legality and enforceability of any such provision in every other respect and of the remaining provisions of this Agreement will not be in any way impaired thereby, it being intended that all of the rights and privileges of the Parties hereto will be enforceable to the fullest extent permitted by Law.

13.11 No Waiver. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver, delay or the failure of any Party to enforce or exercise any term, condition or part of this Agreement at any time or in any one or more instances will not be deemed to be or construed as a waiver of the same or any other term, condition or part, nor will it forfeit any rights, power or privilege to future enforcement thereof. No single or partial exercise of any right, power or privilege will preclude any other or further exercise of such right, power or privilege or the exercise of any other right, power or privilege. To the maximum extent permitted by Law, (a) no claim or right arising out of this Agreement or any of the documents referred to in this Agreement can be discharged by one Party, in whole or in part, by a waiver or renunciation of the claim or right unless in writing signed by the other Party; (b) no waiver that may be given by a Party will be applicable except in the specific instance for which it is given; and (c) no notice to or demand on one Party will be deemed to be a waiver of any obligation of that Party or of the right of the Party giving such notice or demand to take further action without notice or demand as provided in this Agreement or the documents referred to in this Agreement. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

13.12 Relationship of the Parties. Neither Party will have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party will have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party will act solely as an independent contractor, and nothing in this Agreement gives either Party the

power or authority to act for, bind, or commit the other Party in any way. This Agreement is not a partnership agreement. Nothing in this Agreement will be construed to establish a relationship of partners, principal and agent or joint venturers between the Parties or their respective employees or Affiliates. Nothing contained in this Agreement shall be construed to create a "separate entity", "business entity" or "partnership" within the meaning of the U.S. Internal Revenue Code or the regulations thereunder and any foreign equivalents thereto. Neither Technology Partner nor Greenfield will make any statements, representations, or commitments of any kind, or to take any action that is binding on the other, without the prior consent of the other Party to do so.

13.13 English Language. This Agreement was prepared in the English language, which language governs the interpretation of, and any dispute regarding, the terms of this Agreement.

13.14 Counterparts. This Agreement may be executed in one or more counterparts, each of which is an original, but all of which together constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or by PDF. In addition, facsimile or PDF signatures of authorized signatories of any Party will be deemed to be original signatures and will be valid and binding, and delivery of a facsimile or PDF signature by any Party will constitute due execution and delivery of this Agreement.

13.15 Expenses. Each of the Parties will bear its own direct and indirect expenses incurred in connection with the negotiation and preparation of this Agreement and, except as set forth in this Agreement, the performance of the obligations contemplated hereby and thereby.

[*Remainder of this page intentionally left blank*]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized officers as of the Effective Date.

GREENFIELD BIOVENTURES L.P.,

By: _____
Name: Paul Medeiros
Title: President

[redacted]

By: _____
Name: [redacted]
Title: [redacted]

PURDUE PHARMA L.P., solely for purposes of Sections 8.2, 8.4, 9.1, 13.1, 13.7 and 13.8

By: _____
Name: Paul Medeiros
Title: Senior Vice President, Corporate and Business Development

EXHIBIT A

INITIAL DEVELOPMENT PLAN, DEVELOPMENT FEES AND CLINICAL SUPPLY TERMS

[**REDACTED**]

ADDITIONAL DETAILS AS TO TECHNOLOGY PARTNER'S RESPONSIBILITIES AND DEVELOPMENT FEES

[**REDACTED**]

Exhibit B

PHARMACOVIGILANCE AGREEMENT

To be attached.

Exhibit C

QUALITY AGREEMENT

To be attached.

EXHIBIT D

[**REDACTED**]

Exhibit E

PRE-APPROVED TECHNOLOGY PARTNER SUBCONTRACTORS

[**REDACTED**]

SCHEDULE 1

TECHNOLOGY PARTNER PATENTS

[**REDACTED**]

SCHEDULE 2

AUTO INJECTOR SPECIFICATIONS

[**REDACTED**]

SCHEDULE 3

GREENFIELD PATENTS

[**REDACTED**]